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EUSES	European Union System for the Evaluation of Substances
EVA	Ethylene-Vinyl Acetate
GC-LRMS Spectrometry	Gas Chromatography Coupled to Low Resolution Mass Spectrometry
HAR	Agreement on the use of a Commonly Agreed Marking for Cables and Cords complying with Harmonised Specifications
HCl	Hydrogen Chloride
HDPE	High density polyethylene
HFFR	Halogen-free flame retardants
HSE	Health and Safety Executive
IARC	International Agency for Research on Cancer
IDDP	Isodecyl diphenyl phosphate
IPP	Isopropylated triphenyl phosphate
KemI	Swedish Chemicals Agency
LEV	Local Exhaust Ventilation
LCCP	Long-Chained Chlorinated Paraffins
LOAEL	Lowest Observed Adverse Effect Level
LOEC	Lowest Observed Effect Concentration
LRTAP	the Convention on Long Range Transboundary Air Pollution
LSFOH	Low-smoke free- of halogen
MCCP	Medium-Chained Chlorinated Paraffins
MDH	Magnesium dihydroxide
MSW	Municipal Solid Waste
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NR	Natural rubber
ODP	2-ethylhexyl diphenyl phosphate
PE	Polyethene
PEC	Predicted Environmental Concentration
PBT	Persistent Bioaccumulating Toxic
PINFA	Phosphorous, inorganic and nitrogen flame retardants Association
PNEC	Predicted No Effect Concentration
POPs	Regulation (EC) No 850/2004 on Persistent Organic Pollutants
PP	Polypropylene
PPE	Personal Protective Equipment

PROC	Process Category
PRODCOM	"PRODUCTION COMMUNAUTAIRE" (Community Production) for mining, quarrying and manufacturing: sections B and C of the Statistical Classification of Economy Activity in the European Union (NACE 2)
PVC	Poly vinyl chloride
P/vP	Persistent / very Persistent
REACH	Regulation (EU) No 1907/2006 on the registration, evaluation, authorisation and restriction of chemical substances.
RCR	Risk Characterisation Ratios
SBR	Poly-styrene-butadiene rubbers
SCCP	Short-Chained Chlorinated Paraffins
SIN	Substitute It Now
SiR	Silicone rubbers
SME	Small and Medium-sized Enterprise
STP	Sewage treatment plant
TCP	Tricresyl phosphate
TDI	Tolerable Daily Intake
TGD	Technical Guidance Document
TOTM	Tris (2-ethylhexyl) trimellitate
TRA	Targeted Risk Assessment
TSH	Thyroid Stimulating Hormone
TWA	time-weighted average
TXP	Trixylyl phosphate
UK	United Kingdom
UVCB	Substance of Unknown or Variable composition, Complex reaction products or Biological materials
VPE	Vinylethoxysiloxane-propylethoxysiloxane copolymer
vPvB	very Persistent very Bioaccumulating
WEEE	Waste Electrical and Electronic Equipment
ww	wet weight

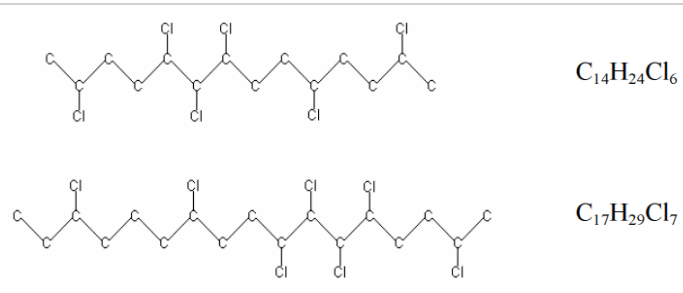
1 Identification, classification and labelling, legal status and use restrictions

1.1 Identification

1.1.1 Name, other identifiers and composition of the substance

Alkanes, C₁₄₋₁₇, chloro (EC No: 287-477-0, CAS No: 85535-85-9), otherwise known as medium-chained chlorinated paraffins (MCCPs) are a group of organic substances with a carbon chain length between 14 and 17 containing varying amounts of chlorine, typically between 40-63% w/w chlorine content as shown in **Table 1** (ECB, 2005). MCCPs are a UVCB substance, comprising of a variety of congeners.

Table 1. Substance identity and composition

Chemical name	Medium-chained chlorinated paraffins (MCCPs)
EC number	287-477-0
CAS number	85535-85-9
IUPAC name	Alkanes, C ₁₄₋₁₇ , chloro
Index number in Annex VI of the CLP Regulation	602-095-00-X
Molecular formula	C _x H _(2x-y+2) Cl _y , where x = 14-17 and y=1-17.
Molecular weight range	233-827 g/mole
Synonyms	Chlorinated paraffin (C ₁₄₋₁₇); chloroalkanes, C ₁₄₋₁₇ ; chloroparaffin; chloroparaffine, C ₁₄₋₁₇ ; medium-chain chlorinated paraffins
Structural formula (examples, indicative of carbon chain length range only)	 C ₁₄ H ₂₄ Cl ₆ C ₁₇ H ₂₉ Cl ₇
Degree of purity	≥99%
Remarks	UVCB substance, commercial mixtures contain less than 1% of LCCPs (long-chain) or SCCPs (short-chain)
Source: (ECB, 2005)	

MCCPs are produced by chlorination of *n*-paraffins in a batch process. Chlorine gas is added to a stirred vessel, which already contains the starting paraffin feedstock. Reaction temperature is between 80 and 100 °C, depending on the length of the paraffin chain.

Commercial products are complex mixtures of isomers but with advanced methods it is now possible to separate and to identify them. The content of MCCP depends on the composition of the raw material, the paraffin feedstock used for their production. For example these feedstocks often contain no more than 1-2% iso-paraffins and <100 mg aromatics per kg.

Chemicals Agency has considered the ongoing work here and that has to some extent delayed the work on this restriction proposal of MCCP under RoHS.

Currently, there are no active EU restrictions that apply to the marketing and use of MCCPs, as far as the REACH Regulation is concerned. Furthermore, there are no known intentions for other measures under the REACH regulation.

1.3.2 Other EU legislative measures

Use of MCCPs is not explicitly restricted under other EU legislation. However, provisions in health and safety and product legislation could affect MCCPs due to their harmonised classification.

Table 6 lists the EU legislation (Directives and Regulations) considered in this study.

Table 6. List of EU legislation considered in the search for restrictions on the use of MCCPs

Legislation	Comments
Pregnant workers Directive 92/85/EEC	MCCPs are classified as having hazardous effects via lactation so employers should conduct risk assessments for any pregnant or breastfeeding workers and decide on the measures to be taken
EU Ecolabel criteria ⁶	According to Article 6(6) of Regulation (EC) No 66/2010 on the EU Ecolabel, the EU Ecolabel cannot not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with Regulation (EC) No 1272/2008 nor to goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 (REACH)
SEVESO III Directive 2012/18/EU	Not explicitly mentioned. However, as it is classified Aquatic Acute 1 and Aquatic Chronic 1, it is included in Part 1 of Annex 1 (Dangerous substances) and establishments holding at least 100 t (lower tier) or 200 t (upper tier) of MCCPs are required to conform to the relevant articles of the Directive (articles 7, 8 & 16 for lower-tier and articles 7, 8, 10, 12 & 16 for upper-tier establishments)

1.3.3 Existing national control measures

In Germany, chlorinated paraffin-containing wastes, e.g. metal working fluids with a content of over 2 grams of halogen per kg of formulation and halogen-containing plasticisers are classified as potentially hazardous waste and are incinerated (BUA, 1992). MCCPs are classified as “WGK2 – hazard to waters”, according to the German Administrative Regulation of Substances Hazardous to Water⁷. In Norway, MCCPs are included in the national ‘List of Priority Substances’ for which emissions are to be substantially reduced by 2010 at the latest (COWI, 2010).

⁶ JRC, product groups EU ecolabel and Green Public Procurement criteria development; available online at: http://susproc.jrc.ec.europa.eu/product_bureau/projects.html, accessed on 16 November 2015. Also see product groups and criteria for imaging equipment, personal computers, notebook computers and televisions at <http://ec.europa.eu/environment/ecolabel/products-groups-and-criteria.html>, last visited on 19 July 2016.

⁷ GESTIS database, available online at: [http://gestis-en.itrust.de/nxt/gateway.dll/gestis_en/000000.xml?f=templates\\$fn=default.htm\\$3.0](http://gestis-en.itrust.de/nxt/gateway.dll/gestis_en/000000.xml?f=templates$fn=default.htm$3.0), accessed on 20 November 2015.

MCCPs have been on the Danish Environmental Protection Agency's (Danish EPA) 'list of undesirable substances' since 1996. This list is intended to act as a signal to and a guideline for substances which should either be restricted or the use of which should stop in the long term.

Short chain chlorinated paraffins (SCCPs, alkanes, C₁₀₋₁₃, chloro) are regulated in the EU since 2002 by a restriction of their use in metal working fluids and fat liquors as substances or as constituents of other substances or preparations in concentrations higher than 1%. Furthermore, SCCPs were included in the candidate list of Substances of Very High Concern under REACH because of their PBT and vPvB properties. Following the inclusion of SCCPs in the POPs Protocol in 2009, SCCPs were in 2012 listed in Annex I of the POP Regulation (EC) No 850/2004 on Persistent Organic Pollutants⁸ thus prohibiting the production, placing on the market and use of SCCPs or preparations containing SCCPs in concentrations greater than 1% by weight or articles containing SCCPs in concentrations greater than 0.15% by weight. The Regulation specifically stated that articles that contain SCCPs in concentrations lower than 0.15% by weight were allowed to be placed on the market and used, as this is the amount of SCCPs that may be present in an article produced with MCCPs. For imported articles containing MCCPs the amount of SCCPs may exceed 0.15% by weight, see text box below. The Regulation allowed the use of conveyor belts in the mining industry and dam sealants containing SCCPs already in use on or before 4 December 2015, and articles containing SCCPs already in use on or before 10 July 2012.

Presence of SCCPs in commercial MCCPs products from China

Recent research in China has looked into the congener profile of carbon and chlorine in technical chlorinated paraffin products available on the Chinese market using GC-LRMS (electron capture negative ionisation). This has shown that for CP-52 (i.e. MCCPs), which account for over 80% of the national Chinese market, C₁₄ carbon chain length was the dominant group, followed by C₁₃ and C₁₅. This demonstrates that the commercial MCCP product C-52 from China is composed of both SCCPs and MCCPs (Yin, 2016). The findings are shown in the figure below

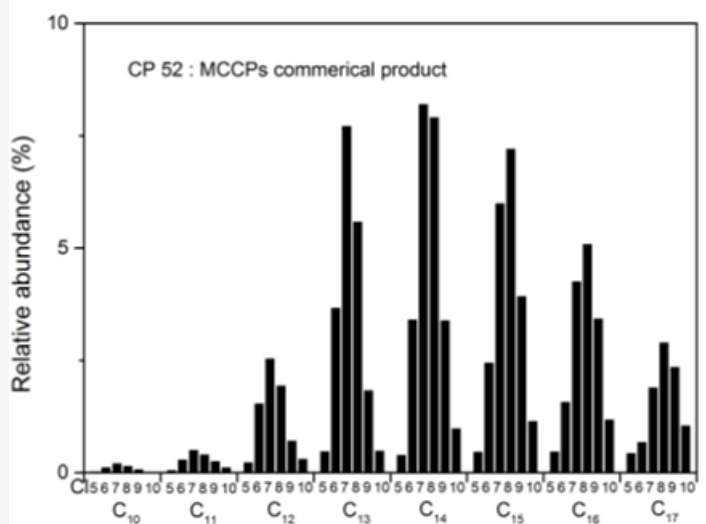


Figure 1: Relative abundance of homologous and congener profile of carbon and chlorine in technical C-52 product in the Chinese market by GC-LRMS (ECNI) (Yin, 2016)

⁸ EC Regulation No. 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC.

2 Use in electrical and electronic equipment

2.1 Function of the substance

Uses of MCCPs identified in literature include (ECB, 2005):

- Secondary plasticiser (extender) in PVC;
- Softeners with flame retardant properties in rubber;
- Plasticisers and flame retardants in adhesives and sealants;
- Plasticisers in paints and varnishes;
- Flame retardants (secondarily) in plastics;
- Extreme pressure additive in metal working/cutting fluids;
- Components of leather fat liquors; and
- Carrier solvent in carbonless copy paper.

The main use of MCCPs is as **secondary plasticiser** (extender) in PVC. The effects of secondary plasticisers are limited when used alone and consequently they are instead used to enhance the plasticising effects of a primary plasticiser (mainly phthalates but also phosphate esters). It is also important to note that MCCPs are significantly cheaper, and this is one of the main reasons that they are used in a wide variety of PVC applications, including cables¹².

In addition, the high chlorine content of some of the MCCP congeners (i.e. >50% wt. Cl) makes them effective as flame retardants and they are used as such in PVC, rubber and other polymers, including polyurethane, polysulphide, acrylic and butyl sealants and adhesives (UK HSE, 2008). These adhesives are used as ‘potting agents’ in electronic equipment to encapsulate, seal and insulate fragile, pressure-sensitive, microelectronic components and printed circuit boards¹³. However, if the main function is flame retardancy, usually LCCPs with high chlorine content are used instead alongside a synergist, such as antimony trioxide (COWI, 2010).

2.2 Uses of MCCPs in EEE

2.2.1 Cable and wire sheathing and insulation

MCCPs predominantly serve as secondary plasticisers in flexible PVC used as sheathing and insulation jackets for cables and wires with rated voltage of less than 250 Volt, according to the RoHS2 Directive’s scope. PVC sheathed cables and wires are used in the vast majority of household electrical and electronic appliances. **Figure 2** indicates where PVC cable jackets and wire insulation are most likely to be found within a cable. The MCCPs used for cable and wire sheathing have chlorination degrees of typically around 50–52% wt. Cl (Öko-Institut, 2008).

¹² A.S. Wilson (1996), *Plasticisers: Selection, Applications and Implications*, Shrewsbury Rapra Technology Ltd, p.19

¹³ American Chemistry Council, ‘Polyurethane Applications’, available online at: <http://polyurethane.americanchemistry.com/Introduction-to-Polyurethanes/Applications>, accessed on 28 November 2015

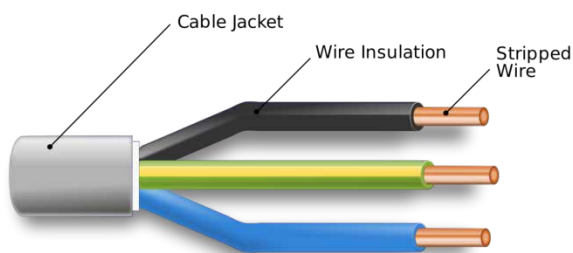


Figure 2: Diagram illustrating location of PVC cable and wire jackets

In general, MCCPs as plasticisers and flame retardants in PVC are typically added at 10-15% w/w of the total plastic. It was commented in consultation that the content can reach up to 20% of the PVC sheathing or insulation of electric cables.

MCCPs can also be used in rubber insulation and sheathing for cables and wires. MCCP content when used in rubbers appears to be lower, compared to PVC cables. A survey on the use of chlorinated paraffins in general in the UK rubber industry identified that MCCPs are used in rubber cable covers at a concentration of 3.8% (Brooke, et al., 2009). Furthermore, a survey in Norway identified two cases with MCCP content of 11% and 2.6% in cables (COWI, 2010).

2.2.2 Adhesives and sealants

Chlorinated paraffins can also be used in polyurethane, polysulphide, acrylic and butyl sealants and adhesives and the MCCPs used in sealants as plasticisers with flame retardant properties generally have a chlorine content of 50–58% wt. Cl (ECB, 2005). **Table 7** summarises the applications of these sealants and adhesives in EEE as presented in the literature.

Table 7. Sealant and adhesives containing chlorinated paraffins used in EEE

Sealant/adhesive	Details of their use
Non-foam polyurethanes	Non-foam polyurethanes, also referred to as “potting compounds,” are used by electrical and electronics industries to protect, seal and insulate fragile, pressure-sensitive, microelectronic components and printed circuit boards. They also act as adhesives and provide solvent, water and extreme temperature resistance ¹⁴
Foam polyurethanes	Typically these foams contain up to 20% MCCP in the pre-polymer (FEICA, 2015). The function of polyurethane products is connected to their flame retardant properties, however, as previously mentioned, it is important to note that MCCPs are not considered to be specific flame retardant additives for plastics due to the degree of chlorination required, which must be between 70–72% (INERIS, 2011). The main markets for polyurethane foam, including foam sheets, are furniture, bedding and automotive – these represent 70% of the total market. However, the remaining 30% of the foam market includes appliances, packaging, electronics and other uses ¹⁵
Polysulphide	Also used for ‘potting’ purposes in electronic equipment

¹⁴ Information available at: <http://polyurethane.americanchemistry.com/Introduction-to-Polyurethanes/Applications>, accessed on 28 October 2015.

¹⁵ Foam Engineers, ‘Open Cell Polyurethane Foam’, at: <http://www.foamengineers.co.uk/foam-manufacturing-suppliers/open-cell-polyurethane-foam/>, accessed on 28 October 2015.

Within a house, there are also a variety of meters that may be used, such as water, gas and electricity meters – all of these could make use of PVC sheathed cables. The European Commission states that the intention is to ‘replace at least 80% of electricity meters with smart meters¹⁸ by 2020 wherever it is cost-effective to do so’¹⁹, consequently a significant number of meters are expected to be disposed of in the coming years, including their cables. **Table 8** lists the types of PVC items that are associated with common household appliances.

Table 8. List of PVC items associated with types of household appliances

Type of Equipment				
TV ^{a,f}	Radios ^{b,c,d,e,f}	Computers ^g	Refrigerators ^{g,h}	Washing machines & tumble dryers ^{g,i}
Mains cable and plug wires	Mains cable and plug wires	Mains cable and plug wires	Mains cable and plug wires	Mains plug and cables
SCART lead	Internal radio antenna	DVI	Wires connecting fridge lighting	Hose
F-Plug connector	Auxiliary cable	HDMI	Wires connecting evaporator	Hose adaptor
S-video	Headphones	USB cables		Ventilation hose
DVI	Wires connecting speakers	IDE cable		
HDMI connector		Serial ATA		
Component connectors		Networking cables		
Composite connectors		S-video		
Digital optical audio		RCA cables		
VGA				
RCA stereo audio				
RF or coaxial cable				
i.Link				
PictBridge				
PVC tablet/computer covers				
Wires for surround sound speakers				
Sources:				
a. http://support.hp.com/us-en/document/c00396708				
b. http://www.radioworld.co.uk/fw-pvc-50-pvc-covered-multi-stranded-flexweave-copper-wire-sold				
c. http://www.ucable.com.my/images/products/UC%20PVC%20Catalogue.pdf				
d. http://www2.mst.dk/udgiv/publications/2008/978-87-7052-733-0/pdf/978-87-7052-734-7.pdf				

¹⁸ Smart meters are electronic gas and electricity meters that automatically send readings to service providers, and provide real-time information to the customer. For example, a smart meter fixed to the electricity supply will inform both the service provider and the customer of how much electricity has been used in that household within a given period of time and the costs incurred.

¹⁹ European Commission, ‘Smart Grids and Meters’, at: <https://ec.europa.eu/energy/en/topics/markets-and-consumers/smart-grids-and-meters>, accessed on 5 November 2015.

Given the decline in the use of PVC compounds in cable manufacture, the suggestion that MCCPs use in EEE has declined would appear to be plausible. Furthermore DEHP and three other phthalates are restricted from use in concentrations over 0.1 % by weight under the RoHS directive starting from 22 July 2019 for the majority of EEE categories. There is no information about any exemption requests regarding use of those phthalates in cables, while a phase out from this use is expected when the restriction is to apply. This further implies that the decrease in use of MCCP would continue.

2.4.2 Imports and exports

For use in PVC and other polymers, it is possible that masterbatch pellets containing MCCPs could be manufactured outside the EU and then imported into the EU for further processing to manufacture the final product. Similarly, such pellets could be manufactured within the EU and exported for subsequent processing. A similar situation may also exist with finished products containing MCCPs. The actual amounts of MCCPs imported into and exported out of the EU are thus very difficult to estimate.

If it is assumed that the qualities and makeup of cables imported are similar to those produced in the EU, and using the assumption that 15,000 t/y of MCCPs are used in cables, it is possible to make a rough estimation of the quantities of MCCPs present in imported cables. Using simple analogy, quantities of MCCPs in imported cables were roughly 2,100 tonnes in 2014²³. However, it must be noted that the quantities of imports and exports are very close, so the net consumption of cables in the EU would be very close to the produced quantities. Therefore, under the same assumptions as above, quantities of MCCP consumed in the EU in the form of cables would be 15,000 t/y.

The actual figure of MCCPs entering the EU market in EEE is uncertain; from one hand, there are indications on a declining use of PVC compounds in European cable manufacturing and a general trend towards a lower consumption of MCCPs in the EU. On the other hand, significant volumes of finished EEE are imported into the EU²⁴ and these may contain MCCPs. We assume that imports and exports of MCCPs in PVC and/or EEE are largely equivalent, so the figure of 15,000 t/y will be used when calculating emissions and assessing the risks to human health and the environment. However, it is possible that this figure is an underestimate. According to Eurostat the import is 2.6 times bigger than the export for certain groups of EEE.

²³ With an EU cable production of 4,774,201 tonnes of cables and an overall MCCP consumption of 15,000 t/y, on average $15,000 \div 4,774,201 = 0.003$ tonnes of MCCPs can be found in one tonne of cables. Using this factor alongside the imported cable tonnage, the volume of MCCPs imported as a cable component can be estimated at $677,081 \times 0.003 = \text{ca. } 2,100$ t/y.

²⁴ As will be shown in Section 5.2.1, the amount of EEE placed on the EU market in 2012 was 9.1 million tonnes. According to the European Environment Agency (see map of import-export flows for EEE at <http://www.eea.europa.eu/data-and-maps/figures/imports-and-exports-of-electrical>), exports of EEE to third countries in 2012 were equivalent to 1.29 million tonnes while imports were equivalent to 3.76 million tonnes. Therefore, within the total EEE consumption in the EU in 2012, EU-made EEE represented $9.1 - 3.76 = 5.34$ million tonnes of consumption. In other words, $5.34 \div 9.1 = 59\%$ of consumption was domestically manufactured EEE and the remaining 41% of EEE consumption was imported from outside the EU.

3 Human health hazard profile

As UVCB substances, MCCPs are heterogeneous compounds that represent significant challenges to hazard characterisation. The four chain lengths (C₁₄₋₁₇) and variable chlorination percentages generate a plethora of distinct heterogeneous substances. It has been suggested that considering MCCPs as a homogeneous substance may be “*misleading*”, highlighting a need to identify groups of relevant MCCPs (ECB, 2007). However, it is not reasonable to expect full toxicological datasets to cover each possibility and, where data are not available on one particular MCCP substance, it may be possible to read across information available from other MCCP substances. In the absence of human epidemiology studies, *in vivo* animal studies have been considered in the reproductive and developmental toxicity evaluations of MCCPs. The information detailed herein has primarily been extracted from the EU Risk Assessment Report (JRC-IHCP, 2011). Where no toxicological information on MCCPs was available, data on the structurally related SCCPs will be used.

3.1 Endpoints of concern

3.1.1 Toxicokinetics, metabolism and distribution

Subsequent to exposure, chlorinated paraffins are widely distributed throughout the liver, kidney, intestine, bone marrow, adipose tissue and ovary. Whilst the metabolic pathways are uncertain, MCCPs may be excreted via the renal, biliary and pulmonary routes (as CO₂), in addition to via lactation in nursing mothers (IPCS, 1996). In rats, the faeces were the major route of MCCP elimination, while excretion via urine and exhaled air was limited, accounting for less than 3% and 0.3%, respectively. Elimination of MCCPs decreases as chlorine content increases. Human skin exposed to C₁₅ chlorinated paraffin for 24 hours absorbed 0.7%, leading to the assumption that a dermal absorption value of 1% was appropriate for risk characterisation (UK HSE, 2008; JRC-IHCP, 2011).

3.1.2 Acute effects

Acute toxicity

There is no indication in the available literature that MCCPs are acutely toxic.

Irritation and sensitisation

No data are available in humans relating to skin or eye irritation. However, based on two standard animal studies, C₁₄₋₁₇ chlorinated paraffins have been shown to cause only slight skin irritation on single exposure. The observation of somewhat more pronounced irritation following repeated application to the skin is considered to be a defatting action. Studies conducted in rabbits indicate that C₁₄₋₁₇ chlorinated paraffins produce only slight eye irritation. Similar findings arising from repeated exposures of the eyes have been seen with SCCPs.

There are no data in relation to respiratory irritation in humans or animals. However, the lack of any reports relating to this endpoint given the widespread use of the substances, suggest that they lack the potential to cause such an effect. The low skin and eye irritation potential and generally unreactive nature of this group of substances lends further support to this view.

No evidence of skin sensitisation was produced in guinea pig maximisation tests using C₁₄₋₁₇ (40 or 45% chlorination). Overall, the available data and generally unreactive nature of MCCPs (and data on SCCPs) indicate an absence of skin sensitisation potential (UK HSE, 2008; JRC-IHCP, 2011).

3.1.3 Repeated dose toxicity

A NOAEL of 23 mg/kg/day is identified for repeated dose toxicity based upon effects seen in rat kidney (increased weight at the next dose level of 222 mg/kg/day and “chronic nephritis” and tubular pigmentation at 625 mg/kg/day). It is noted that at 222 mg/kg/day there were also slight decreases in plasma triglycerides and cholesterol levels.

In another study, 10 male and 10 female Sprague-Dawley rats received 0, 5, 50, 500 or 5,000 ppm C₁₄₋₁₇ MCCP (52% chlorination) by dietary admixture for 90 days (Poon et al., 1995), which equated to dose levels of approximately 0, 0.4, 4, 36 and 360 mg/kg/day in males and 0, 0.4, 4, 42 and 420 mg/kg/day in females. No treatment-related deaths or clinical signs were observed and there were no adverse effect on bodyweight gain or food consumption. At the highest dose, there was indication for liver and kidney damage in males, but significant increases in absolute and relative liver and kidney weights in females.

Exposure to a MCCP (40% chlorination) has been shown to lead to thyroid effects (follicular cell hypertrophy and hyperplasia) in two studies in rats. The first study (Wyatt, et al., 1993) provides evidence in support of the thyroid effects being attributable to stimulation of this organ arising from a negative feedback control which ultimately gives rise to hypertrophy and hyperplasia in this organ. The second study (Wyatt, et al., 1997) discussed thyroid follicular cell hypertrophy and hyperplasia observed in this study are considered to have arisen as a result of continued stimulation by thyroid stimulating hormone (TSH). It may well have been the case in this study the homeostatic balance had been reset such that increased TSH levels resulted in “normal” T₄ levels and therefore, no detectable decrease in this hormone upon measurement. In addition, no toxicologically significant effects on thyroid hormones and TSH levels were observed up to the top dose of 222/242 mg/kg/day (males/females) in a well-conducted 90-day study in rats. The EU RAR consider the manifested effect mechanisms and the apparent association with the observed liver effects, together with the highlighted differences in T₄ binding capacity between humans and rats, and concluded that the thyroid effects produced in rats would be of little relevance to human health at relevant levels of exposure (UK HSE, 2008; JRC-IHCP, 2011).

3.1.4 Mutagenicity and carcinogenicity

Whilst SCCP C₁₂ chlorinated paraffins (60% chlorine by weight) are listed by the International Agency for Research on Cancer (IARC) as “*Possible Carcinogens*” and in the U.S. National Toxicology Program (NTP) carcinogen list as “*reasonably anticipated to be a carcinogen*”, MCCPs (C₁₄₋₁₇ of 40–52% chlorination) are not mutagenic in the Ames test, gene mutation assays or *in vivo* bone marrow tests. Carcinogenicity data from exposed human populations or toxicology studies are not available.

In the absence of experimental carcinogenicity data on MCCPs, given the similarities between MCCPs and SCCPs in physicochemical properties and in the results obtained in relation to other toxicological endpoints, particularly the effects seen on the liver, thyroid and kidneys on repeated exposure, it seems reasonable to presume that the carcinogenic potential of MCCPs will be similar, at least in qualitative terms, to that of SCCPs. SCCPs have been

investigated in animal studies and found to induce liver, thyroid and kidney tubular cell adenomas and carcinomas. On mechanistic considerations, the liver and thyroid tumours were considered to be of little or no relevance to human health. The underlying mechanism for the kidney tumours has not been fully elucidated. However, there is recent mechanistic evidence to show that α 2u-binding is probably the primary mechanism for kidney tumour formation induced by SCCPs in male rats. The available evidence strongly suggests that the underlying mechanism would not be relevant to humans. Still a risk characterisation for the carcinogenicity endpoint will be conducted using the same NOAEL of 23 mg/kg/day for repeated dose effects on the kidney (JRC-IHCP, 2011).

3.1.5 Reproductive and developmental effects

From the studies available, an overall NOAEL of 47 mg/kg/day (600 ppm) MCCP as a maternal dose can be identified for these effects mediated via lactation. However, it should be noted that the effects (11% reduction in pup survival and related haemorrhaging) observed at the LOAEL (74 mg/kg/day; 1000 ppm) were not statistically significant, but were supported by a dose-response at higher exposure levels.

Haemorrhaging was also seen in one study at the time of parturition in 16% of dams given 538 mg/kg/day (6250 ppm) MCCPs, but not up to 100 mg/kg (1200 ppm) in other studies. The NOAEL of 100 mg/kg/day (1200 ppm) is therefore selected for the risk characterisation of haemorrhaging effects potentially occurring in pregnant women at the time of parturition (JRC-IHCP, 2011).

3.1.6 MCCP exposure studies and review of human studies

Indirect exposure to humans via the local and regional environment has been estimated at 32 $\mu\text{g kg}^{-1}/\text{day}$ and 0.3 $\mu\text{g kg}^{-1}/\text{day}$, respectively. Dietary exposure contributed 71-100% of the total intake. The Swedish Chemicals Agency detected MCCP levels of 14 ng g^{-1} fat (1.1–30 ng g^{-1} fat weight) in pooled Swedish breast milk collected between 1996 and 2010 (Danish EPA, 2014). In addition, a study in England detected median MCCP concentrations of 21 ng g^{-1} fat (6.2–320 ng g^{-1} fat) in 25 breast milk samples between 2001 and 2002 (Thomas, et al., 2006).

3.2 Existing guidance values

3.2.1 Point of departure (NOAEL)

Acute toxicity for MCCPs is very low, so the starting point for the derivation on a Derived No Effect Level (DNEL) will be for chronic hazards. The main effects seen in repeated dose studies are on the liver, thyroid and kidneys. The 23 mg/kg bw/day value calculated for kidney effects in rats after dietary exposure can be used as the most reliable value. This value translates to 41 mg/m³ – 8h TWA for human workers.

The NOAEL value for effects via lactation is 47 mg/kg/day. As mentioned above, however, the effects observed at the LOAEL (74 mg/kg/day; 1000 ppm) were not statistically significant, but were supported by a dose-response at higher exposure levels.

Finally, as shown above, a NOAEL of 100 mg/kg/day (1200 ppm) was selected for the risk characterisation of haemorrhaging effects potentially occurring in pregnant women at the time of parturition.

3.2.2 Derived No Effect Levels (DNELs)

The Annex XV transitional report prepared by the UK CA in 2008 contains a calculation of DNELs for those endpoints that the EU RAR identified in 2005. The RAR concluded that long-term repeated exposure to MCCPs has the potential to cause adverse effects in the kidney. There are also concerns identified for exposed pregnant workers and their breast-fed babies due to vitamin K deficiency. The dose descriptors for these effects have been derived from oral studies in animals as there are no data available for the inhalation route and in humans. Owing to the different nature of the effects seen and the differences in dose-response relationship, separate endpoint-specific DNELs for the kidney toxicity, the effects at the time of parturition and the effects mediated via lactation in order to identify the critical long-term DNEL were calculated. The report only calculated DNELs for workers but not for the general population. **Table 11** presents the DNELs as calculated in that report. The critical DNELs selected in the report are marked in bold and italics.

An oral DNEL for the assessment of man exposed via the environment (water, food and air) has been derived from the NOAEL of 23 mg/kg bw/day, identified for repeated dose toxicity based upon effects seen in rat kidney (see section 3.1.3 above). Assuming 100% oral absorption in man compared to 50% in rat and applying a total assessment factor of 100 gives a DNEL of 0.115 mg/kg/day.

Table 11. DNEL calculation for worker DNEL systemic effects in Annex XV transitional report

Target population (worker)	Starting point	AF*	DNEL	Comments
<i>Inhalation route for kidney effects/carcinogenicity</i>	41 mg/m ³ – 8h TWA (23 mg/kg bw/day)	25	<i>1.6 mg/m³</i>	Converted from animals to humans and adjusted for exposure and potential differences among workers
Inhalation route for effects at the time of parturition	176 mg/m ³ – 8h TWA (100 mg/kg bw/day)	25	7 mg/m ³	Converted from animals to humans and adjusted for exposure and potential differences among workers. Address residual uncertainty in dose response
Inhalation route for effects via lactation	83 mg/m ³ – 8h TWA (47 mg/kg bw/day)	25	3 mg/m ³	Converted from animals to humans and adjusted for exposure and potential differences among workers. Address residual uncertainty in dose response
<i>Dermal route</i>	1,150 mg/kg bw/day (50 mg/kg bw.day)	100	<i>11.5 mg/kg bw/day</i>	Starting point adjusted for different absorption in oral (50%) and dermal route (1%)
*: Assessment Factor. It is used to derive the DNEL Source: Annex XV Transitional Report (UK CA, 2008)				

3.2.3 Occupational exposure limits

With regard to occupational exposure, a long term limit value for MCCPs in air has been set in Germany at 0.3 ppm (6 mg/m³) of inhalable aerosol for 8-hour exposure. A short term

limit value of 2.4 ppm of inhalable aerosol (15 minute TWA) also applies in Germany²⁵. The GESTIS database of limit values (maintained by the Institute for Occupational Safety and Health of the German Social Accident Insurance – IFA) lists no other countries as having an OEL on MCCPs.

3.2.4 Tolerable daily intake

For the general population, a tolerable daily intake (TDI) of 100 $\mu\text{g kg}^{-1}$ bw/day for non-neoplastic effects has been calculated in response to a 10 mg kg^{-1} bw/day NOAEL, adopting a safety factor of 100 for inter- and intra-species variation (IPCS, 1996). However, the Canadian EPA calculated a TDI of 5.7 $\mu\text{g kg}^{-1}$ bw/day from a sub-chronic study NOAEL of 0.4 mg kg^{-1} bw/day (Environment Canada, 1993).

²⁵ GESTIS database of international limit values, available online at: <http://limitvalue.ifa.dguv.de/>, accessed online on 20 November 2015.

4 Environmental health hazard profile

4.1 Endpoints of concern

4.1.1 Aquatic compartment, including sediment

Environmental hazard information has been reviewed in the EU RAR that was produced under the ESR. Since then, few new studies have been reviewed. The PBT/vPvB evaluation report for MCCPs bases its analysis on MCCP toxicity starting from the information contained in the EU RAR.

Aquatic toxicity has been observed in tests with invertebrates over chronic exposures. The test substance was a C₁₄₋₁₇ MCCP with 52% wt. chlorination and the test subject was *Daphnia magna*. The test produced a 21-day NOEC of 10 µg/l for *D.magna*. Furthermore, a 48 h EC₅₀ of 5.9 µg/l was determined for the same species. This information is sufficient to fulfil the T criterion in the PBT assessment of MCCPs.

Tests on fish, algae and other invertebrate species did not show signs of toxicity over long exposures. However, testing on sediment organisms (*Lumbriculus variegatus*) produced a NOEC for mortality/reproduction of 130 mg/kg dry weight, which is equivalent to 50 mg/kg on a wet weight basis. The substance used was a 52% wt. chlorine C₁₄₋₁₇ MCCP (Thompson, et al., 2001). The same NOEC for the same substance was produced in a study on *Hyalella azteca* for growth of females over 28 days (Thompson, et al., 2002).

4.1.2 Terrestrial compartment

In trophic order, no mortality or abnormal symptoms were observed in mallard ducks (*Anas platyrhynchos*) or ring-necked pheasants (*Phasianus colchius*), consequent to a single oral dose of C₁₄₋₁₇ MCCP (52% chlorination) of 10,280 mg kg⁻¹ bw or 24,606 mg/kg bw, respectively. In addition, no toxicity was observed following dietary exposure to 24,063 mg/kg feed *Eisenia fetida* (red worm) was the most sensitive soil organism, presenting a 56-day NOEC of 280 mg/kg dry soil.

The PNEC_{oral} of 10 mg/kg food for secondary poisoning which was ultimately used in the EU RAR is based on a NOAEL of 300 mg/kg food from a 90-day study with rats (assessment factor: 30).

4.1.3 Sewage treatment systems

According to the EU RAR, studies on the effects of MCCPs on bacteria show that the lowest threshold concentration reported to cause effects was 800 mg/l. This is equivalent to a NOEC/LOEC, so it was selected for the calculation of the PNEC for STP (ECB, 2007).

4.2 Environmental fate properties

4.2.1 Persistence

Abiotic degradation

According to the results of the EU RAR, atmospheric half-life for MCCPs was estimated at 1-2 days. Howard et al. (1975) reported that MCCPs with chlorine content of 45% wt Cl and

52% wt Cl were not decomposed when exposed to high energy light (13% of energy in the 220-280 nm range) in petroleum ether. They concluded that direct photolysis of MCCPs is unlikely to be a significant degradation pathway in the environment. In aqueous systems, MCCPs are not expected to degrade significantly by abiotic processes such as hydrolysis.

Biodegradation

Madeley and Birtley determined the biodegradability of several commercial MCCPs using extended BOD (biological oxygen demand) tests (Madeley & Birtley, 1980). The substances were tested as emulsions at concentrations of 2, 10 and 20 mg/l using both acclimated and unacclimated microorganisms. The results indicate that the potential for degradation of the chlorinated paraffin appears to increase with decreasing chlorination. From the available information, MCCPs can be considered to be non-biodegradable in such test systems.

Similar results from more recent sources are included in the report on evaluation of PBT/vPvB properties (ECHA 2013). Biodegradability of MCCP congeners strongly depends on the carbon chain length and the degree of chlorination. However, while MCCPs with low chlorination levels (ca. 45% wt chlorine) are readily biodegradable and highly chlorinated MCCPs (>60% wt chlorine) are not, there is a grey area where MCCP congeners with intermediate levels of chlorination are concerned. ECHA has therefore in the context of Substance Evaluation, requested simulation degradation studies on a C₁₄ chlorinated n-alkane with a chlorine content of 50-52% by weight, a C₁₄ chlorinated n-alkane with a chlorine content of 55-60% by weight and a C₁₅ chlorinated n-alkane with a chlorine content of around 51% by weight. Monitoring evidence suggests that MCCPs with chlorine contents of around 55% by weight may persist for a long time in sediments. However, it should be noted that these estimates are uncertain, particularly in the 45–50% chlorine content range and, although considered useful for identifying constituents that potentially meet or do not meet the REACH Annex XIII criteria for persistence, they do not provide definitive proof of this.

4.2.2 Bioaccumulation

According to the EU RAR, MCCPs have log K_{ow} in the range 4.47-8.21, with a typical value around 7. This is a strong indication that MCCPs bioaccumulate. Indeed, laboratory studies have shown that MCCPs bioaccumulate; fish bioconcentration factors (BCFs) ranged from 1000 to 15000 for two MCCP structures (C₁₅ 51% wt. chlorination and C₁₄ 45% wt. chlorination respectively) (Thompson & Vaughan, 2013). Modelling and read-across approaches suggest that the non-growth corrected fish BCF is >2,000 l/kg for C₁₄, ~45% wt. chlorination and C₁₄, ca. 52% wt. chlorination example structures. The EU RAR uses a BCF value of 1087 l/kg measured in rainbow trout (*Oncorhynchus mykiss*) for a C₁₅, 51% wt. chlorination substance (ECB, 2005). However, the value is neither growth corrected nor lipid normalised (as the REACH Guidance document recommends to normalise to a 5% lipid content if possible), so it is likely that the BCF for the specific MCCP component is underestimated. Indeed, it is commented in the PBT evaluation sheet published by ECHA that the BCF was re-evaluated and that the growth corrected BCF is around 1,833–2,082 l/kg, which constitutes a borderline case for bioaccumulation (ECHA, 2013). BCF-values of 6660 (whole body, steady state) and 9140 (kinetic) were reported for a C₁₄, 45% wt. chlorination congener according to a well-documented OECD 305 test from 2010 referenced in the registration dossier of MCCP. The respective values when normalised for 5% lipid content were 3230 and 4440 (which, if normalised for growth, would exceed 5000).

Biotransformation results in Juvenile rainbow trout (*Oncorhynchus mykiss*) presented a negative correlation with Log K_{ow} and the total number of carbon and chlorine atoms (range - 0.00028 to 8.4). Increasing carbon-chain length and chlorine content increased the bioaccumulation by decreasing the partition-based diffusion and metabolic elimination (Fisk, et al., 2000). Nevertheless, it must be noted that MCCPs with longer chains (C_{16-17}) seem to be of no concern, according to the PBT evaluation sheet (ECHA, 2013).

In conclusion, it seems that individual MCCP-congeners e.g. C_{14} , 45% wt. chlorination meet the B-criterion as well as the vB criterion of Reach in Annex XIII. However, information for other congeners is uncertain and varies by carbon chain length and degree of chlorination.

The EU RAR highlights some other important points that need to be taken into consideration when evaluating bioaccumulation of MCCPs (ECB, 2007):

- There is a few studies available which show that MCCPs are present in marine fish and marine mammals (including top predators such as porpoise and fin whale);
- MCCPs or their metabolites have been found to have relatively long elimination half-lives in a number of species including fish, oligochaetes and laboratory mammals; and
- MCCPs have been demonstrated to cause effects in young rats exposed via breast milk, and have been determined to be present (at low levels) in breast milk in the general population. It is possible that MCCPs may also be present in mothers' milk of mammals in the wild.

A recent review of the field data by Thompson & Vaughan (2013) suggested that trophic biomagnification of MCCPs is not occurring. In contrast to this, recent studies (Zeng, 2017) performed in China implies that trophic magnification is occurring in marine food webs. They studied a marine food web where finless porpoise (*Neophocaena phocaenoides*) and Indo-Pacific humpback dolphins (*Sousa chinensis*) were the top predators. BMF-factors for \sum MCCPs between the two cetacean species and different prey fishes ranged from 1.4 to 11 for finless porpoise and between 23 and 58 for Indo-Pacific humpback. In addition, a trophic magnification factor (TMF) for \sum MCCPs of 4.79 was calculated for the marine food web including mollusks, crustaceans, fish and marine mammals (porpoise and dolphin). The significantly higher proportion ($p < 0.05$) C_{14} MCCP in in porpoise and dolphin compared to their prey implies that C_{14} has a larger bioavailability and bioaccumulation potential than C_{15-17} . In another Chinese study (Huang, 2017) MCCP-levels were measured in different species of fish in the Liaodong. The most abundant MCCP congener in the fish was C_{14} accounting for 61 - 96% of total MCCP. $C_{14}Cl_7$ and $C_{14}Cl_8$ were the most abundant groups. Huang *et al* also investigated biomagnification in an aquatic food web including different invertebrates with fish as top-predator. The calculated TMFs of MCCP congeners ranged from 0.23 to 2.92 with the highest value for the $C_{14}Cl_5$ congener. The linear relationship was however weak with a r^2 -value of 0.15 and a p-value of 0.26 indicating that biomagnification was not pronounced in this purely aquatic food web. In addition, high levels found in terrestrial organisms and birds of prey (**section 6.2.2**) suggests that MCCPs accumulates in terrestrial ecosystems/food chains.

4.3 Summary on PBT/vPvB assessment

4.3.1 Assessment against REACH PBT criteria

MCCPs meet the screening criterion for P/vP. There are no data from degradation simulation tests with the substance itself. However, the related substance, SCCPs, meet the formal P and vP criteria (EC, 2008), with mineralisation half-lives of around 1,630-1790 days in freshwater sediment and 335-680 days in marine sediment. These data suggest that MCCPs would also be present within the meaning of the PBT criteria and it is considered unlikely that further testing would change this interpretation.

Based on the available information on bioaccumulation examined in the EU RAR and during the more recent Substance Evaluation, the balance of evidence is that C₁₄ congeners with 40-50% wt. chlorination meet the criteria for very bioaccumulative substances (BCF > 5000) while C₁₄ congeners with 50-55% wt. chlorination meet the criteria for bioaccumulative substances (BCF > 2000); C₁₄ with 55-65% wt. chlorination are a borderline case. Data available on a C₁₅, 51% wt. chlorination congener indicate that it constitutes a borderline case, while information on congeners with longer carbon chains is based on predicted data and shows lower bioaccumulation potential.

Table 12, adapted from ECHA's decision on Substance Evaluation for MCCPs (ECHA, 2014), shows the estimated P and B properties of MCCP congeners.

Table 12. Estimated P & B properties of potential constituents of MCCPs

Carbon chain no.	Chlorine content (w/w)			
	~40-50%	~50-55%	~55-65%	>65%
14	Not P vB	P? B	P? Borderline B	P Not B?
15	P? Not B	P? Borderline B	P Not B	P Not B
16	P? Not B	P? Not B	P Not B	P Not B
17	P? Not B	P? Not B	P Not B	P Not B

Source: Adapted from ECHA's substance evaluation decision for MCCPs (ECHA, 2014)

The T criterion is met, based on the 21-day NOEC of 0.01 mg/l in *Daphnia magna*.

4.4 Guidance values (PNECs)

The Predicted No Effect Concentrations for MCCPs were initially calculated in the EU RAR, using the NOECs determined there. Examining the registration information in the ECHA Dissemination Database showed that the registrants used the same starting points to derive the PNECs.

Table 13 presents the PNECs calculated in the EU RAR and also used by the REACH registrants of MCCPs.

Table 13. PNEC calculations for MCCPs

Compartment	Starting point	AF	PNEC	Comments
PNEC _{water} (freshwater)	10 µg/l from 21-day study on <i>D.magna</i>	10	1 µg/l	EU RAR only derived PNEC values for freshwater, not marine environment
PNEC _{marine}	10 µg/l from 21-day study on <i>D.magna</i>	50	0.2 µg/l	A higher AF was used than for freshwater PNEC, probably because available NOEC was on freshwater species
PNEC _{sediment}	50 mg/kg wet wt. on <i>L.variegatus</i> & <i>H.azteca</i>	10	5 mg/kg wet wt.	Registration dossier uses the dry weight PNEC
	130 mg/kg dry wt. on <i>L.variegatus</i> & <i>H.azteca</i>		13 mg/kg dry wt.	
PNEC _{STP}	800 mg/l on bacteria	10	80 mg/l	Starting point is the lowest reported concentration in which no effects were observed which is equivalent to NOEC/LOEC
PNEC _{soil}	106 mg/kg soil wet wt. on <i>E.fetida</i>	10	10.6 mg/kg soil wet wt.	Registration dossier uses the dry weight PNEC
	(119 mg/kg soil dry wt.) [*]		11.9 mg/kg soil dry wt.	
PNEC _{oral} (secondary poisoning)	300 mg/kg food from 90-day study on rats	30	10 mg/kg food	The EU RAR had initially calculated a PNEC _{oral} of 0.17 mg/kg food, but it was later revised to 10 mg/kg food after evaluation of new data
<p>*: Starting point is product of back calculation, as it is not clearly stated in the database. Research on the terrestrial toxicity studies included in the endpoint indicates it is the same study as the one used in the EU RAR. Source: EU RAR (2005, 2007), ECHA Dissemination Database</p>				

5 Waste management of electrical and electronic equipment

5.1 Description of waste streams

5.1.1 Main materials containing MCCPs

As discussed above, MCCPs are used almost exclusively in plastics and rubbers. These are used mainly for cables, but also for other plastic parts of EEE. Their main functions are as secondary plasticisers and flame retardants, so it is unlikely that they will be intentionally present in other materials.

As shown in **Table 9** above, according to Danish EPA, in 2006 54% of MCCPs were used in PVC and 11% in rubber and other polymers. It is assumed that the split between PVC and

other polymers is the same in EEE as in overall, then 83% of MCCPs in EEE are used in PVC and 17% in other polymers. For reasons of simplicity, the analysis below will assume that all MCCPs can be found in PVC (cables).

Finally, as established earlier in this document, a consumption of 15,000 t/y of MCCP in EEE in the EU can be assumed.

5.1.2 WEEE categories containing MCCPs

It must be noted that cables used for the transfer of electrical currents and electromagnetic fields meet the definition of EEE as set out in Article 3(1)(a) of the WEEE Directive 2012/19/EU. Cables that are components of another EEE (internal – permanently attached – or externally connected and removable, but sold together or marketed/shipped for use with the EEE), fall within the scope of the recast WEEE Directive (coming into force in 2018) if the EEE is in scope of WEEE. Cables placed on the market individually, that are not part of another EEE, are considered as EEE themselves²⁶ and fall within the scope of WEEE. Cables that does not fall within the remit of the recast WEEE Directive (coming into force in 2018) are non-finished cables i.e. cable reels without plugs.

In the cases where manufacturers/importers etc. of cables within EEE not in scope of WEEE do not have to arrange and pay a fee (based on quantity placed on the market) for their recovery, like the manufacturers of other EEE do, it does not mean that cables within waste EEE are not collected for processing and recycling. Cables contain valuable metals, which are the key output of recycling operations. Therefore, the analysis here will assume that during the separate collection of WEEE, cables forming part of EEE are not ignored.

Having in mind the non-applicability of the recast WEEE Directive, we may look into its Annex III of the WEEE Directive to identify categories of appliances which may be of relevance to (i.e. may contain) PVC cables that contain MCCPs. These are:

- Category 1: Temperature exchange equipment (e.g. refrigerators);
- Category 2: Screens, monitors and equipment containing screens having a surface greater than 100 cm²;
- Category 4: Large equipment (any external dimension more than 50 cm);
- Category 5: Small equipment (no external dimension more than 50 cm); and
- Category 6: Small IT and telecommunication equipment (any external dimension more than 50 cm).

Category 3, lamps, are not included above as they are mostly irrelevant. It is assumed that cables containing MCCPs are used in the other appliances allocated within the recast WEEE Directive under the above categories indiscriminately.

5.2 Waste treatment processes applied to WEEE containing MCCPs

5.2.1 Treatment processes applied to the WEEE

Table 14 was adapted from the RoHS Annex II Dossier template developed by the Austrian Federal Environment Agency. Cat3 (lamps) is of no relevance to this analysis. As noted

²⁶ European Commission, FAQ on the WEEE Directive, available online at: <http://ec.europa.eu/environment/waste/weee/pdf/faq.pdf> (accessed on 3 August 2016).

above, the categories are used as indicative and do not suggest applicability of the provisions of the recast WEEE Directive.

Table 14. Initial treatment processes applied

Initial treatment processes	The substance is present in appliances belonging to:					
	Cat1	Cat2	Cat3	Cat4	Cat5	Cat6
For WEEE collected separately						
Collection and transport	x	x	x	x	x	x
Dedicated treatment processes for cooling & freezing appliances	x					
Dedicated treatment processes for screens		x				
Dedicated treatment processes for lamps			x			
Manual dismantling	x	x		x	x	x
Shredding (and automated sorting)	x			x	x	x
For WEEE not collected separately						
Landfilling (of residual waste)		x	x		x	x
Mechanical treatment (of residual waste)		x	x		x	x
Incineration		x	x		x	x
Uncontrolled treatment in third countries	x	x		x	x	x
Cat1: Temperature exchange equipment (e.g. refrigerators)						
Cat2: Screens, monitors and equipment containing screens having a surface greater than 100 cm ²						
Cat3: Lamps						
Cat4: Large equipment (any external dimension more than 50 cm)						
Cat5: Small equipment (no external dimension more than 50 cm)						
Cat6: Small IT and telecommunication equipment (any external dimension more than 50 cm)						

WEEE, which is collected separately, is manually dismantled or shredded, typically in large-scale metal shredders which can be combined with automated material sorting or specific shredders. External cables under the WEEE Directive must be removed and this can be performed before or after the mechanical or manual breaking of EEE, or the cables can be removed as part of the shredder residue (DEFRA, 2006). From these shredding processes MCCPs may end up in mixed plastic enriched fractions.

WEEE that is not collected separately will likely be incinerated or landfilled.

WEEE plastics can also be treated in third countries. According to the Countering WEEE Illegal Trade (CWIT) project in Europe in 2012, WEEE which did not end up in the officially reported amounts of collection and recycling systems was exported, recycled under non-compliant conditions in Europe or scavenged for valuable parts²⁷. This is however outside the scope of the analysis. Thus, the volume of WEEE entering the waste handling process e.g. collection, recycling and disposal is lower than the theoretical available volume if also taken into account the volumes ending up as export to third countries, recycled under non-compliant conditions in Europe or scavenged for valuable parts.

²⁷ Countering WEEE Illegal Trade (CWIT) project in Europe in 2012 available at <http://www.cwitproject.eu/wp-content/uploads/2015/09/CWIT-Final-Report.pdf> accessed on 26 October 2017

Key points	For WEEE collected separately, the key treatment processes are:
	<ul style="list-style-type: none"> · Manual dismantling; and · Shredding.
Key points	For WEEE not collected separately, the key treatment processes include:
	<ul style="list-style-type: none"> · Landfilling (as part of Municipal Solid Waste (MSW)); · Incineration (as part of MSW); and · Export and uncontrolled disposal in third countries

5.2.2 Treatment processes applied to wastes derived from WEEE

Table 15 presents an overview of relevant treatment processes of waste materials from WEEE, as shown in the RoHS Annex II Dossier template. The only relevant ones are plastics, cables and possibly electronic components.

Table 15. Treatment processes for wastes derived from WEEE

Treatment processes for wastes derived from WEEE treatment	The substance is present in the following main component/material								
	Ferrous metals	Non-ferrous metals	Plastics	Electronic components	Cables	Glass	Powders	Fluids	Others
Under current operational conditions in the EU									
Storage of secondary wastes	x	x	x	x	x	x	x	x	x
Shredding and automated sorting of secondary wastes	x	x	x	x	x	x			
Recycling of ferrous metals	x								
Recycling of NE metals		x			x				
Recycling of plastics			x		x				
Recycling of glass						x			
Recycling as building material						x			x
Landfilling of residues	(x)	x	x	x	x	x	x		
Incineration of residues		x	x	x	x		x		x
Co-incineration of residues			x	x					x
Dedicated processes for hazardous residues				x			x	x	
Under uncontrolled conditions									
Acid leaching				x					
Grilling/desoldering				x					
Uncontrolled combustion			x	x	x		x		x
Uncontrolled dumping of residues			x	x		x	x		x

As described by the Austrian Federal Environment Agency in a similar RoHS dossier for DEHP present in PVC cables (Umweltbundesamt, 2014), cables derived from dismantling of WEEE are sent to cable shredders. These are usually cutting mills combined with a sorting technique, including air separation, sieving, vibration desks or wet density separation. The main aim of a cable shredder (indeed the primary goal of cable recycling) is to recover the metals, especially copper. The obtained non-metal fraction is composed of the various polymers used in cables i.e. PVC, PE, HDPE, VPE and rubber, as well as a small fraction of metals (Umweltbundesamt, 2014).

Having generated the mixed plastic fraction, the following treatment options arise:

- **Landfilling:** mixed plastic waste of low value may be sent to municipal landfills (assuming no hazardous materials are present). Note that many countries have already banned landfilling of untreated organic wastes (e.g. Germany) or are planning to do so (VinylPlus, 2014);
- **Incineration:** mixed plastic waste of low value may be sent to municipal incinerators. It is of interest that PVC has a heat value of approximately 19 megajoules per kilogram (MJ/kg), which is higher than the average heat value of municipal waste (11 MJ/kg) used to generate electricity. Therefore, it can make a useful contribution as a fuel for power generation through waste incineration (VinylPlus, 2014);
- **Recycling:** cable recycling has traditionally focused on metal recovery and less in recovering the plastic fraction, as noted above. This is evident in uncontrolled recovery of materials from cables and other waste (e.g. used tyres), which is usually through incineration of the plastic to get to the metal content. It is known that through Recovynyl, over 100,000 tonnes of PVC cable waste were collected in 2015²⁸. In 2016 was around 150,000 tonnes of PVC cable waste recycled²⁹. There are a number of options available:
 - *Mechanical recycling:* this covers processes which do not break polymer chains into small components. It is well suited to pre-sorted, single waste-stream waste. Within the mechanical recycling category, two subcategories are defined: conventional and non-conventional technologies.
 - Conventional technologies describe long-established processes which usually sort, shred and separate components within the waste stream resulting in granulated recycled PVC that can be used in the manufacture of new products;
 - Non-conventional technologies cover alternative processes that often use solvent based processes or pre-processing to access PVC from more difficult or complex waste streams. The Vinyloop® chemical process is such an example.
 - *Feedstock recycling:* this is more suitable for unsorted plastic mixtures and waste streams containing composite materials. These processes involve (usually) thermal treatment of the PVC waste stream with recovery of hydrogen chloride that can then be returned to the PVC production process or used in other processes (VinylPlus, 2014).

It is understood that feedstock recycling is of limited use today for PVC cable recycling; therefore, the focus will be on mechanical recycling.

Recycled flexible PVC is predominantly used in the manufacture of materials used in manufacturing road equipment, roofing and insulating membranes, footwear, mats, garden hoses, ropes, etc. The metal and other material impurities in plastic from cables typically make the recyclate unsuitable for direct reuse in cable insulation, although recycling into new cable production may still occur.

It must also be noted that there is a considerable flow of recyclate (i.e. sorted, post-consumer plastic waste) to countries outside the EU. According to information collected from an industry stakeholder, a significant portion of PVC cable waste (roughly 40%) is exported to non-EU countries for treatment. **Table 16** summarises this stakeholder's estimations of PVC cable waste treatment.

Table 16. Industry stakeholder's estimation of methods used for PVC cable waste treatment

²⁸ VinylPlus, available at <http://www.vinylplus.eu/progress/annual-progress/2013-2>, accessed on 22 July 2016.

²⁹ VinylPlus, available at <https://vinylplus.eu/uploads/Modules/Bannersreport/vinylplus-progress-report-2017.pdf>, accessed on 19 October 2017.

Export to non-EU	Reuse in EU	Recycle locally	Landfill locally	Incinerate locally
40%	0%	25%	20%	15%

Key points	<p>For MCCP-containing (PVC) waste that is extracted from WEEE collected separately, the key treatment processes are:</p> <ul style="list-style-type: none"> · Landfilling; · Incineration; · Conventional mechanical recycling; · Non-conventional mechanical recycling; and · Export uncontrolled disposal in third countries
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5.3 Flow of MCCPs during waste treatment processes relevant for assessment under RoHS

5.3.1 Split of WEEE collection routes by volume

WEEE collected separately

In 2012³⁰, the amount of EEE put on the market was 9.1 million tonnes. In the same year, 3.5 million tonnes or 6.9 kg/inhabitant of WEEE were collected separately in the EU and 3.6 million tonnes of WEEE were treated, of which 2.6 million tonnes were recovered. The recovered amount included 2.4 million tonnes of recycled WEEE (i.e. reprocessed into a product) and 0.2 million tonnes that were used for energy production³¹. However, it is unknown how much plastic the WEEE contained and which was treated and recovered.

Two key assumptions are made at this point:

- It is assumed that the MCCP input into waste management by WEEE corresponds to the total quantity of MCCPs put on the European market via EEE, i.e. 15,000 tonnes annually. Actual WEEE generation at a given time, e.g. based on models taking into account the life-time of particular equipment, is not considered for the present assessment (but note the discussion above suggesting a lifetime of 10-20 years); and
- It is assumed that, in terms of weight, the amount of WEEE generated is equal to that of EEE products being placed on the EU market (i.e. 9.1 million tonnes per year).

Using the figures above, we can calculate that $3.5 \text{ million} \div 9.1 \text{ million} = \text{ca. } 40\%$ of WEEE generated is collected and treated in the EU. This is assumed to contain a corresponding 40% of the MCCP content of waste EEE, i.e. $40\% \times 15,000 = 6,000 \text{ t/y}$.

WEEE collected separately and reused

It is estimated that a small percentage (ca. 1% according to Eurostat data for 2012) of WEEE may be reused. This may contain $1\% \times 15,000 = 150 \text{ t/y}$ MCCPs. This element is ignored in the analysis below.

³⁰ Data for 2013 are available but incomplete and therefore EU waste data for 2012 are used here.

³¹ Eurostat, available at http://ec.europa.eu/eurostat/statistics-explained/index.php/Waste_statistics_-_electrical_and_electronic_equipment#Electrical_and_electronic_equipment_put_on_the_market_by_country (accessed on 22 July 2016).

WEEE collected as municipal solid waste

Some waste EEE, particularly smaller appliances, may simply be placed in household waste rather than be collected separately as WEEE. The percentage of total WEEE that is disposed of in this way is uncertain. Looking at assumptions made by the Austrian Federal Environment Agency in the past, the percentage is 13% (Umweltbundesamt, 2014). For MCCPs, this would mean that $13\% \times 15,000 = 1,950$ t/y would end up in household waste.

WEEE exported to third countries or remains unaccounted for

The remaining fraction, i.e. $100\% - 40\% - 13\% - 1\% = 46\%$ is assumed to be exported to third countries or be otherwise unaccounted for. This contains $46\% \times 15,000 = 6,900$ t/y MCCPs. According to the CWIT project in Europe 57% of all the WEEE discarded in 2012 was exported, recycled under non-compliant conditions in Europe or scavenged for valuable parts²⁸. Here in the report the assumption is 59 %; WEEE exported to third countries, remains unaccounted or is present in MSW alongside other household waste.

Key points	The fate of MCCPs in WEEE arising in the EU is assumed to be as follows: <ul style="list-style-type: none">• 6,000 t/y is present in WEEE collected separately;• 150 t/y is present in WEEE collected separately and reused within the EU;• 1,950 t/y is present in MSW alongside other household waste; and• 6,900 t/y is exported in WEEE to third countries or remains unaccounted for
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5.3.2 Split of WEEE waste treatment processes in the EU

Treatment of WEEE collected separately

It was explained above that for WEEE collected separately, the key treatment processes are manual dismantling and shredding. It is also assumed that, irrespective of the applicability of the recast WEEE Directive on cables integrated into EEE, of all WEEE being separately collected as an initial treatment (before shredding or manual dismantling) 80% of the cables are cut off (Umweltbundesamt, 2014). Therefore $6,000 \times 80\% = 4,800$ tonnes of MCCPs per year could theoretically become available for subsequent recycling.

For the remaining 20% (i.e. 1,200 t/y), there needs to be consideration of whether manual dismantling or shredding will apply. The split between the two is based on the approach taken by the Austrian Federal Environment Agency (Umweltbundesamt, 2014), and considers the latest information on WEEE volumes collected across the different WEEE categories³². As shown in **Table 17**, overall, 69% (by weight) of separately collected WEEE is subject to shredding, while the remaining 31% is subject to manual dismantling.

³² Eurostat, Waste electrical and electronic equipment (WEEE) collected, by EEE category, 2012, available at: [http://ec.europa.eu/eurostat/statistics-explained/index.php/File:Waste_electrical_and_electronic_equipment_\(WEEE\)_collected,_by_EEE_category,_2012.png](http://ec.europa.eu/eurostat/statistics-explained/index.php/File:Waste_electrical_and_electronic_equipment_(WEEE)_collected,_by_EEE_category,_2012.png) (accessed on 22 July 2016).

Table 17. Shredding vs. manual dismantling of separately collected WEEE

WEEE category	Volumes collected in 2012 (tonnes)	Shredding share (%)	Manual dismantling share (%)	Overall split
Large household appliances	1,451,142	80%	20%	Shredding: 69% Manual dismantling: 31%
Small household appliances	219,100	100%	0%	
IT and telecom equipment	598,408	30%	70%	
Consumer equipment	554,657	70%	30%	
Total	2,823,307	-	-	
Sources : Umweltbundesamt (2014); Eurostat				

In other words:

- $69\% \times 1,200 = 828$ t/y of MCCPs are present during shredding of WEEE; and
- $31\% \times 1,200 = 372$ t/y of MCCPs are present during manual dismantling of WEEE.

Treatment of WEEE collected in unsorted Municipal Solid Waste

Information to the European Environment Agency (EEA, 2013) indicates that landfilling was twice as widely used as incineration across 32 countries in 2010. However, more recent data from Eurostat for year 2014 provide the following shares³³:

- Landfill: 66 million tonnes;
- Incineration: 64 million tonnes;
- Recycling: 66 million tonnes;
- Composting: 38 million tonnes; and
- Other: 5 million tonnes.

If we only focus on landfilling and incineration, the split can be assumed to be 51-49%. In other words:

- $51\% \times 1,950 = 995$ t/y of MCCPs are present during landfilling of unsorted MSW; and
- $49\% \times 1,950 = 955$ t/y of MCCPs are present during incineration of unsorted MSW.

Treatment of WEEE outside the EU

This falls outside the scope of this analysis.

5.3.3 Split of waste (PVC) material treatment processes in the EU

As shown above, 6,000 t/y is present in WEEE collected separately and of this 80%, i.e. $80\% \times 6,000 = 4,800$ t/y, is actually cut and potentially available for recycling. The remainder is assumed to be disposed of by a mixture of landfilling (51% or 612 t/y MCCPs) and incineration (49% or 588 t/y MCCPs).

³³ Eurostat, Municipal waste landfilled, incinerated, recycled and composted in the EU-27, 1995 to 2014, available at: http://ec.europa.eu/eurostat/statistics-explained/index.php/File:Municipal_waste_landfilled,_incinerated,_recycled_and_composted_in_the_EU-27,_1995_to_2014_new.png (accessed on 22 July 2016).

In relation to the share of (PVC) cables that is available for recycling, it cannot be assumed that the majority of it will indeed be recycled. **Table 16** explained the fate of PVC waste in the EU, as described by a key industry stakeholder. It has also been advised by industry stakeholders that the vast majority of PVC cable waste recycling is undertaken by conventional mechanical recycling rather than the Vinyloop® process. To err on the side of caution, we will assume that all PVC cable waste recycling is undertaken by conventional methods.

Based on the above and the percentages presented in **Table 16**, we may consider the following split:

- $40\% \times 4,800 = 1,920$ t/y MCCPs are exported to third countries within PVC waste;
- $25\% \times 4,800 = 1,200$ t/y MCCPs are mechanically recycled within the EU;
- $20\% \times 4,800 = 960$ t/y MCCPs are landfilled as PVC waste within the EU; and
- $15\% \times 4,800 = 720$ t/y MCCPs are incinerated as PVC waste within the EU.

Key points	The fate of MCCPs in waste extracted from separately collected WEEE arising in the EU is assumed to be as follows:
	• 1,200 t/y is mechanically recycled with conventional methods within the EU;
	• 1,572 t/y is landfilled within the EU;
	• 1,308 t/y is incinerated within the EU; and
	• 1,920 t/y is exported in PVC waste to third countries (or otherwise subject to uncontrolled disposal)

5.3.4 Treatment processes of relevance to the risk assessment

It has been shown above that the relevant waste treatment options include:

Table 18. Summary of disposal pathways of relevance to MCCP-containing EEE

Lifecycle stage	Collection & separation	Recycling	Landfilling	Incineration	Uncontrolled disposal or export
WEEE collection and treatment	ü	ü	ü	ü	ü
PVC waste collection and treatment	ü	ü	ü	ü	ü

The actual processes of interest and their importance can be described as follows.

Table 19. Importance of waste disposal processes for risk assessment purposes

Lifecycle stage	Process	Description	Importance
WEEE collection and treatment	Manual dismantling of separately collected WEEE	During this process no mechanical or thermal treatment is required so releases of MCCPs to the air, water and soil would be presumed to be low	Very low
	Shredding	Particles of PVC that may contain MCCPs may be generated during the shredding of larger WEEE articles. A considerable number of treatment	High

		installations may be involved in WEEE shredding across the EU	
	Landfilling	Landfilling will take place in appropriately selected landfills operated in accordance with prevailing EU and national legislation. Releases in that case are expected mainly due to leaching, since MCCPs have very low volatility	Low
	Incineration	Under controlled conditions it is likely that 100% of the MCCP will be destroyed (Danish EPA, 2014). The incineration process should not lead to the formation of dioxins and furans as incinerators have equipment to prevent this (Danish EPA, 2011). However, incomplete incineration can result in the formation of dioxins and furans from the chlorine content of the MCCPs (KemI, 2015). High thermal treatment can also result in the leaking and emission of chlorinated paraffins (Swedish EPA, 2011)	Low (Very Low if under controlled conditions)
	Export or uncontrolled disposal	No information is available on these processes and they are considered of no relevance to the analysis of risks within the EU. Where uncontrolled disposal takes place, emissions of MCCPs could be higher as a result of the absence of RMMs	Very low
PVC waste collection and treatment	Shredding as a first step in recycling	See above. Conventional mechanical recycling of PVC cable waste can involve shredding of materials which can potentially release particles containing MCCPs	High
	Mechanical recycling of shredded PVC cable waste	Mechanical recycling covers processes which do not break polymer chains into small components. It is well suited to pre-sorted, single waste-stream waste. Relevant processes include: <ul style="list-style-type: none"> - Formulation of recycled soft PVC containing MCCPs in compounds and dry blends - Industrial use of recycled soft PVC containing MCCPs in polymer processing by calendaring, extrusion, compression and injection moulding to produce PVC articles* 	High
	Landfilling	See above; releases are expected mainly due to leaching, since MCCPs have very low volatility	Low
	Incineration	See above; no releases expected under controlled incineration conditions	Low (Very Low if under controlled conditions)
	Export or uncontrolled disposal	No information is available on these processes and they are considered of no relevance to the analysis of risks within the EU	Very low
* information obtained from a recent Application for Authorisation for DEHP by Vinyloop Ferrara SpA and others, available at http://echa.europa.eu/documents/10162/d141e4e0-6e73-44c9-b7e7-957d72d997ae (accessed on 27 July 2016)			

It is reiterated here that MCCPs are used in plastics (mainly in PVC) and in rubber. However, in the absence of more detailed information, it is assumed that the entire amount of MCCPs in EEE is found in PVC articles (NB. this is assumed to be a conservative assumption as release factors for rubber may be lower than PVC (plastic) as per ECHA's guidance document R.18 on exposure assessment during the waste stage).

5.4 Releases from WEEE treatment processes

5.4.1 Releases during shredding of WEEE collected separately

Information specific to releases of plastic additives during the processing of WEEE is not available, therefore a series of assumptions need to be made.

The Austrian Federal Environment Agency (Umweltbundesamt, 2014) has presented an approach to estimating dust releases from the shredding of WEEE which has been taken into account in this analysis. The Austrian Federal Environment Agency refers to a study commissioned by the European Commission³⁴ according to which the overall annual release of PM₁₀ (particulate matter of diameter less than or equal to 10 µm) from European car shredders is 2,100 tonnes resulting from manipulation of fluff and fines. This is based on an assumption 18% generation of fines/dust from materials treated in a shredder and an emission factor of the dry material of 1 g/kg (Umweltbundesamt, 2014).

The following assumptions were made for MCCPs:

- The total input of MCCPs into WEEE shredders was estimated to be 828 t/y (see Section 5.3.2);
- 90% of the MCCPs input into a shredder are transferred to fluff/fines/dust³⁵;
- 0.1% of fluff/fines/dust is emitted diffusely via PM₁₀ (under dry conditions, watering of the material and other measures for prevention of diffuse emissions will reduce the percentage by one order of magnitude)³⁶.

Using the above figures, it can be estimated that between $(828 \times 90\% \times 0.1\% \times 10\% =) 0.075$ t/y and $(4,140 \times 90\% \times 0.1\% =) 0.75$ t/y of MCCPs are released to the air during the shredding of MCCP-containing WEEE. Expressed as a release factor, the range would be: 0.09-0.9 g/kg. As the Austrian Federal Environment Agency notes, the actual order of magnitude will depend on the degree to which BAT (Best Available Technology) for preventing diffuse emissions from handling of shredded materials including e.g. encapsulation of aggregates or wetting of materials is applied (Umweltbundesamt, 2014).

The Austrian Federal Environment Agency further makes the following assumptions:

- Not all shredders in the EU apply BAT, thus emissions after de-dusting can be based on the upper value for BAT-AELs (Average Emission Levels), i.e. 20 mg/Nm³;
- An exhaust air flow of 20,000 Nm³/h, and a treatment quantity of 60 t WEEE per hour were assumed;
- The concentration of the substance of concern in dust is the same as in the processed WEEE. For MCCPs, this would be $15,000 \text{ t MCCPs} \div 9.1 \text{ million t WEEE} = 1.65 \text{ g/kg}$.

³⁴ EC (2007): Data gathering and impact assessment for a review and possible widening of the scope of the IPPC Directive in relation to waste treatment activities, Study N° 07010401/2006/445820/FRA/G1.

³⁵ This is the assumption made by Umweltbundesamt for DEHP (another plasticiser) based on the findings of Morf, L. & Taverna, R. (2004): Metallische und nichtmetallische Stoffe im Elektroschrott, Stoffflussanalyse.

³⁶ Based on the 2007 EC study referred to above.

Based on these assumptions the total release factor for MCCPs lost to air via residual dust emissions is 0.006 g/kg^{37} with a total annual release of $828 \times 0.0084 = \text{ca. } 7 \text{ kg/y}$.

The overall release factors will thus be:

- Air: 9.66×10^{-5} to 9.066×10^{-4} ;
- Water: nil;
- Soil: nil.

5.4.2 Releases during shredding of PVC cable waste

Similar to the above analysis, releases of plastic additives during the processing of PVC cable waste need to be based on a series of assumptions. The release factors used above for WEEE shredding can be assumed to apply here for PVC cable waste shredding. It has been shown above that the tonnage of MCCPs present in PVC cable waste that is subject to recycling with shredding as an initial process step is 1,200 t/y. Therefore, the total annual releases of MCCPs to air in the form of dust will include:

- $(1,200 \times 0.09 =)$ 108 kg to $(1,200 \times 0.9 =)$ 1,080 kg MCCPs emitted via diffuse emissions each year; and
- $(1,200 \times 0.0066 =)$ ca. 8 kg MCCPs are emitted after the de-duster each year.

The overall release factors will thus be the same as those shown for WEEE shredding above:

- Air: 9.66×10^{-5} to 9.066×10^{-4} ;
- Water: nil;
- Soil: nil.

5.4.3 Releases during PVC cable waste recycling

There are several sources that could be considered for obtaining environmental release factors for the process of recycling of PVC cable waste. A useful source of the description of the steps involved can be found in a recent Application for Authorisation for the continued use of DEHP-containing PVC recyclate by a group of companies, which is available on the ECHA website³⁸ describes the steps involved for obtaining environmental release factors for the process of recycling of PVC cable waste. Details are provided below.

³⁷ If the limit on WEEE dust emission is 20 mg/Nm^3 or $2 \times 10^{-7} \text{ t/Nm}^3$, then in the space of 1 hour, $2 \times 10^{-7} \text{ t/Nm}^3 \times 20,000 \text{ Nm}^3/\text{h} = 4 \times 10^{-4}$ tonnes of WEEE dust will be emitted. Since every hour 60 tonnes of WEEE enters the process, the air release factor is $4 \times 10^{-4} \text{ t} / 60 \text{ t} = 0.0000066 \text{ t/t}$ or, put differently 0.0066 g/kg .

³⁸ Available at: <http://echa.europa.eu/documents/10162/d141e4e0-6e73-44c9-b7e7-957d72d997ae> (accessed on 27 July 2016).

Table 20. Industrial processes involved in the recycling of PVC cable waste

REACH use (Exposure Scenario)	Description	Relevant Process Category (PROC) numbers	Relevant Environmental Release Category (ERC) numbers
Formulation	Formulation of recycled soft PVC containing DEHP in compounds and dry blends	1, 2, 3, 4, 8a, 8b, 14, 15	3
Industrial	Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles	2, 3, 4, 6, 8a, 8b, 14, 21	5

Source: Application for Authorisation for DEHP by Vinyloop Ferrara SpA and others

As far as environmental release factors are concerned, factors specific to recycling processes do not appear to be available, so, by way of a proxy, factors relevant to compounding and conversion of 'virgin' PVC can be used. Examples are provided below.

Table 21. Release factors for MCCPs in PVC cable waste recycling

Source	Activity	Release factors		Other/Notes
		Air	Water	
(UK CA, 2008)	Compounding – secondary plasticiser	0.03%	0.01%	These are likely to be overestimates, especially for air, as they refer to dry blending, which does not take place when using recycle 50 % of these emissions will be released to air and 50 % will eventually be released to waste water (through condensation and subsequent washing/cleaning of equipment, etc.).
	Calendering	0.15%	See right	
	Extrusion	0.03%		
	Injection moulding	0.03%		
(OECD, 2009)	Plasticisers – Compounding	0.001%	0.001 %	Low volatility group
	Plasticisers – Conversion - Calendering	0.005%	0.005 %	
	Plasticisers – Conversion – Extrusion	0.001%	0.001 %	
	Plasticisers – Conversion – Injection moulding	0.001%	0.001 %	
	Flame retardants – Compounding	0.011%	0.001 %	For powders of particle size >40 µm, low volatility group

	Flame retardants – Conversion	0.003%	0.003 %	Partially open process
ECHA Guidance Document on CSA R16 (using ERC numbers shown in Table 22)	Formulation of recycled soft PVC – ERC3	30% max	0.25% max	Soil: 0.1%
	Industrial use of recycled soft PVC containing MCCPs – ERC5	50% max	50% max	Soil: 1%

It cannot be certain what the end products of recycling are, so we cannot speculate on what the mix of calendering, extrusion and injection would be. In addition, it is considered prudent and conservative to assume that the highest release factors used in the UK CA Restriction report will apply. Therefore, the most appropriate environmental release factors would be:

- Compounding:
 - Air: 0.03%;
 - Water: 0.01%;
- Conversion (assuming calendering which shows the highest release factor):
 - Air: $0.15\% \times 50\% = 0.075\%$; and
 - Water: $0.15\% \times 50\% = 0.075\%$.

The amount of MCCPs present in PVC cable waste that is subject to recycling is 1,200 t/y³⁹. Therefore, the total annual releases of MCCPs from the recycling process can be estimated to be:

- Compounding:
 - Air: $1,200 \times 0.03\% = 0.36$ t/y;
 - Water: $1,200 \times 0.01\% = 0.12$ t/y;
- Conversion:
 - Air: $1,200 \times 0.075\% = 0.9$ t/y; and
 - Water: $1,200 \times 0.075\% = 0.9$ t/y.

Notably the Recovinyl website⁴⁰ identifies a total of 52 companies involved in cable recycling in the EU.

5.4.4 Releases during landfilling and incineration of waste

Environmental release factors for landfilling and incineration can be found in ECHA's Guidance Document R.18 on exposure assessment during the waste stage. These are specific to MCCPs as this group of substances is used as an example in the Guidance.

³⁹ Any losses arising from the shredding step are disregarded.

⁴⁰ Recovinyl recyclers, available at: http://www.recovinyl.com/all-recyclers?field_cert_recylers_country2_tid=All&field_materials_tid=66 (accessed on 27 July 2016).

Table 22. Release factors for MCCPs during landfilling and incineration

Activity	Type	Release factors		Notes
		Air	Water	
Landfill	Municipal waste	0.24%	0.824%	Effectiveness of risk management measures has been taken into account
Incineration	Municipal waste	0.005%	0.00285%	

Source: ECHA Guidance Document R.18

The volumes of MCCPs sent to landfills and incineration can be summarised as follows:

Table 23: Industrial processes involved in the recycling of PVC cable waste

Disposal route	Material sent for disposal	Tonnage	Total tonnage
Landfill	MCCPs in WEEE in unsorted MSW	995 t/y	2,567 t/y
	MCCPs in WEEE subject to manual dismantling and shredding (51% of a total of 1,200 t/y)	612 t/y	
	MCCPs in PVC waste that is not sent to recycling	960 t/y	
Incineration	MCCPs in WEEE in unsorted MSW	955 t/y	2,263 t/y
	MCCPs in WEEE subject to manual dismantling and shredding (49% of a total of 1,200 t/y)	588 t/y	
	MCCPs in PVC waste that is not sent to recycling	720 t/y	

The next table summarises the EU-wide estimate releases of MCCPs from landfilling and incineration. The estimates for incineration are likely to be overestimates. Under controlled conditions, MCCPs should be destroyed during incineration, thus the actual releases could be considered to be very low.

Table 24. Environmental releases of MCCPs during landfilling and incineration

Activity	MCCP tonnage	Release factors		Environmental releases in the EU	
		Air	Water	Air	Water
Landfill	2,567 t/y	0.24%	0.824%	6.2 t/y	21.2 t/y
Incineration	2,263 t/y	0.005%	0.00285%	0.11 t/y	0.06 t/y

As regards the number of installations involved in the above processes, the following details are available:

- **Landfills:** 8,400 operating in the EU with releases occurring over 365 days a year (as per ECHA's Guidance Document R.18); and
- **Incinerators:** 500-700 thermal treatment installations plus 115 hazardous waste incinerators operating in the EU with releases occurring over 330 days a year (as per ECHA's on information requirements and chemical safety assessment, Chapter R.18).

5.4.5 Summary of releases from WEEE treatment

Table 25 summarises the release factors discussed above, while Table 26 shows the total MCCP releases from each process.

Table 25. Release factors for MCCPs released during relevant WEEE management operations

Process resulting in environmental releases of MCCPs	Release factor per compartment (unitless)	
	Air	Water
Shredding of WEEE	0.0009066 (max)	-
Shredding of PVC cable waste	0.0009066 (max)	-
PVC recyclate compounding	0.0003	0.0001
PVC recyclate conversion	0.00075	0.00075
Landfilling of WEEE and PVC waste	0.0024	0.00824
Incineration WEEE and PVC waste	0.00005	0.0000285

Table 26. Total releases of MCCPs from WEEE management operations

Process resulting in environmental releases of MCCPs	MCCP tonnage	Total EU releases	
		Air	Water
Shredding of WEEE	828 t/y	0.75 t/y (max)	-
Shredding of PVC cable waste	1200 t/y	1.09 t/y (max)	-
PVC recyclate compounding		0.36 t/y	0.12 t/y
PVC recyclate conversion		0.9 t/y	0.9 t/y
Landfilling of WEEE and PVC waste	2567 t/y	6.2 t/y	21.2 t/y
Incineration of WEEE and PVC waste	2263 t/y	0.11 t/y	0.06 t/y
Total		7.73-9.37 t/y	22.2 t/y

6 Exposure estimation during WEEE treatment

6.1 Human exposure estimation

6.1.1 Exposure of workers of WEEE processing plants

Exposure of workers in WEEE processing and PVC waste recycling plants to MCCPs can occur during the processes of shredding and recycling, where generation of dust and vapours from the operations carried out there is more likely. In incineration plants, there is little exposure of workers to MCCPs, which are destroyed during incineration. Chlorinated paraffins may be a source of chlorine emissions, which in turn may result in the production of polychlorinated dioxins and furans. In general, incinerator facilities have the necessary controls in place to minimise formation of such substances, so MCCPs should not lead to increased emissions (ECB, 2005).

In order to estimate the exposure of workers to MCCPs during WEEE treatment through shredding and recycling (via re-melting, compounding of plastic parts containing MCCPs and converting these to new PVC articles) ECETOC's TRA 3 (European Centre for Ecotoxicology and Toxicology of Chemicals' Targeted Risk Assessment 3) exposure assessment tool has been used. This is a Tier 1 tool mainly used for assessing worker exposure during earlier lifecycle stages of a substance (i.e. manufacturing, formulation, industrial and/or professional use). Waste stage is not within the scope of exposure assessment for REACH. However, the PROC use descriptors, which are used for codifying the relevant processes where exposure to the substance occurs, can be applied to shredding and recycling processes.

Table 27 shows some key physicochemical information for MCCPs used in the analysis.

Table 27. Substance identification parameters used in ECETOC TRA modelling

Parameter	Value used
General description	Medium-chain chlorinated paraffins
CAS No.	85535-85-9
EC No.	287-477-0
Molecular weight (g/mol)	405
Vapour pressure (Pa; temperature range 15-25 °C)	2.70E-04
Water solubility (mg/l; temperature range 15-25 °C)	0.027
LogKow	7
Biodegradability test result	Not biodegradable

In **Table 43** in Annex 1 shows the key scenario assumptions made in estimating worker exposure using the ECETOC TRA model. There are essentially four activities considered:

- Shredding of WEEE that is collected separately;
- Shredding of PVC cable waste;
- Formulation of PVC recyclate; and
- Conversion of PVC recyclate into new PVC articles.

For shredding, **PROC24** (High (mechanical) energy work-up of substances bound in/on materials and/or articles) is used. For formulation and conversion of PVC, the PROC numbers shown in a recent Application for Authorisation by three recyclers have been used. Other parameters applied in a conservative approach include:

- In shredding, it was assumed that the substance was a solid with medium dustiness;
- Duration of activity is assumed to be 8 hours (>4 hours) in all processes;
- Shredding is assumed to take place outdoors in a professional setting and workers wear no protective equipment. Recycling (formulation and conversion) takes place indoors with local exhaust ventilation present but no use of respiratory protective equipment or gloves.

The results of the calculations are shown in **Table 44** in Annex 1.

6.1.2 Consumer exposure

Consumer exposure to MCCPs is not considered relevant in this case. Consumers may be exposed indirectly, via the environment. This is examined in more detail later in the report.

6.1.3 Monitoring data

No monitoring data of worker exposure to MCCPs during WEEE shredding, PVC cable waste shredding and PVC formulation and compounding can be readily found in the literature.

6.2 Environmental exposure estimation

6.2.1 Exposure from waste management

Direct releases of MCCPs during WEEE treatment may occur to air and water, but less so to soil. Nevertheless, due to the substance's persistence and the environmental distribution of emissions, it is likely that it will be found in all environmental compartments. In order to estimate the predicted environmental concentrations (PECs), the EUSES (European Union System for the Evaluation of Substances) 2.1.2 tool was used. Evaluation was carried out for all relevant processes, i.e. shredding, formulation and compounding, incineration and landfilling.

As no suitable emission tables or special scenarios have been integrated into EUSES, the local emissions in **Table 28** have been used as input. MCCPs are a UVCB substance, comprising of a variety of congeners. In order to carry out the assessment a generic representative substance was selected with the following properties:

- Molecular weight: 405 g/mol;
- Melting point: -20°C;
- Boiling point: 200°C;
- Vapour pressure at 20°C: 2.7×10^{-4} Pa;
- Water solubility at room temp: 0.027 mg/l; and
- $\log K_{ow}$: 7.

Table 28 presents some selected EUSES parameters that were used as input for this assessment.

Table 28. Selected EUSES input parameters

Parameter	Input		
Run	Environmental: local & regional scale Man exposed via the environment (local & regional scale)		
Assessment mode	Interactive		
Chemical class for K _{oc} – QSAR	Predominantly hydrophobics		
Bioconcentration factor in fish	2,082 l/kg (for a C ₁₅ MCCP component with 51% wt. chlorination, see Section 4.2.2)		
Biodegradability	Not biodegradable		
Production volume of chemical in the EU	6,858 t/y (this is the volume of MCCPs subject to waste treatment within the EU and is based on the figures shown in Table 26 and includes the tonnages of MCCPS present during WEEE shredding, PVC waste shredding and recycling, landfilling of WEEE and PVC waste and incineration of WEEE and PVC waste)		
Industry category Use category Use pattern	Shredding of WEEE ⁴¹	15/0: Other	MCCP tonnage: 828 t/y
		47: Softeners	Fraction of the main local source ⁴² : 0.0002 × 44 ⁴³ = 0.0088
		Waste treatment	Release factor to air: 0.0009066
		15/0: Other	MCCP tonnage: 1,200 t/y
		47: Softeners	Fraction of the main local source: 0.1 ⁴⁴

⁴¹ According to the latest draft BREF Document for Waste Treatment (available at: http://eippcb.jrc.ec.europa.eu/reference/BREF/WTbref_1812.pdf), about 350 mixed scrap shredders were operating in Europe in 2014. In addition due to the WEEE Directive, dedicated WEEE treatment facilities have also been established in the last 15 years. The Austrian Federal Environment Agency refers to 450 installations and this is the number used here.

⁴² This calculation is based on the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.18 (available at: https://echa.europa.eu/documents/10162/13632/r18_v2_final_en.pdf). Pages 92-93 and Table R.18-21 of this guidance document indicate that for dispersive uses, the default dispersiveness factor of 0.0002 should be multiplied by a conservative concentration factor relevant to the number of waste treatment installations. The concentration factors are shown in Table R.18-21.

⁴³ We assume 450 WEEE shredding installations. The concentration factor is thus $20,000 \div 450 = 44$.

⁴⁴ The Recovinyl website (http://www.recovinyl.com/all-recyclers?field_cert_recylers_country2_tid=All&field_materials_tid=66) identifies a total of 52 cable recyclers in the EU. We assume this number to also represent the number of relevant PVC shredders in the EU. As we do not know how the relevant PVC waste tonnage would be distributed among them, we use a conservative fraction of the main local source of 0.1.

Shredding of PVC waste	Waste treatment	Release factor to air: 0.0009066	
PVC formulation	11: Polymers industry 47: Softeners Polymer processing Thermoplastics: additives, pigments, fillers Industrial use	MCCP tonnage: As above	Fraction of the main local source: 0.4 (default for the industry and use category)
		Release factor to air: 0.0003 Release factor to water: 0.0001	
PVC conversion	11: Polymers industry 47: Softeners Polymer processing Thermoplastics: additives, pigments, fillers Industrial use	MCCP tonnage: As above	Fraction of the main local source: 0.4 (default for the industry and use category)
		Release factor to air: 0.00075 Release factor to water: 0.00075	
Landfilling of WEEE	4: Electrical/electronic engineering industry 47: Softeners Waste treatment	MCCP tonnage: 1,607 t/y	Fraction of the main local source: $0.0002 \times 2.38^{45} = 0.000476$
		Release factor to air: 0.0024 Release factor to water: 0.00824	
Landfilling of PVC waste	11: Polymers industry 47: Softeners Polymer processing Thermoplastics: additives, pigments, fillers Waste treatment	MCCP tonnage: 960 t/y	Fraction of the main local source: $0.0002 \times 2.38^{46} = 0.000476$
		Release factor to air: 0.0024 Release factor to water: 0.00824	
Incineration of WEEE	4: Electrical/electronic engineering industry 47: Softeners Waste treatment	MCCP tonnage: 1,544 t/y	Fraction of the main local source: $0.0002 \times 28^{47} = 0.0056$
		Release factor to air: 0.00005 Release factor to water: 0.0000285	
	11: Polymers industry	MCCP tonnage: 720 t/y	

⁴⁵ Concentration factor given in the Guidance document, Chapter R.18.

⁴⁷ We assume 600 municipal thermal treatment installations and 115 hazardous waste treatment incinerators. The concentration factor is thus $20,000 \div 715 = 28$.

⁴⁷ We assume 600 municipal thermal treatment installations and 115 hazardous waste treatment incinerators. The concentration factor is thus $20,000 \div 715 = 28$.

	Incineration of PVC waste	47: Softeners Polymer processing Thermoplastics: additives, pigments, fillers Waste treatment	Fraction of the main local source: $0.0002 \times 28 = 0.0056$ Release factor to air: 0.00005 Release factor to water: 0.0000285
Number of emission days per year	Landfilling: 365 Shredding, incineration: 330 Formulation, conversion: 220		
STP	Shredding, landfilling, incineration: Bypass STP (for local freshwater assessment) Formulation, conversion: Use STP (for local freshwater assessment)		

The derived regional and local PECs are shown in the two tables that follow. The figures presented are the outputs of the EUSES software when the inputs shown in **Table 28** are used.

Table 29. Regional PEC values for MCCP releases as estimated by EUSES

Regional PEC according to EUSES calculations	Value
Regional PEC in surface water (total)	6.37x10 ⁻⁵ mg/l
Regional PEC in seawater (total)	5.91x10 ⁻⁶ mg/l
Regional PEC in surface water (dissolved)	3.38x10 ⁻⁵ mg/l
Regional PEC in seawater (dissolved)	4.56x10 ⁻⁶ mg/l
Regional PEC in air (total)	1.21x10 ⁻⁶ mg/m ³
Regional PEC in agricultural soil (total)	0.872 mg/kg ww
Regional PEC in pore water of agricultural soil (total)	8.39x10 ⁻⁵ mg/kg ww
Regional PEC in natural soil (total)	0.108 mg/kg ww
Regional PEC in industrial soil (total)	0.182 mg/kg ww
Regional PEC in sediment (total)	0.864 mg/kg ww
Regional PEC in seawater sediment (total)	0.116 mg/kg ww

Table 30: Local environmental PEC values for MCCP releases as estimated by EUSES

Local parameter	Unit	Shredding WEEE	Shredding PVC	Formulating PVC	Conversion PVC	Landfill WEEE & PVC waste	Incineration WEEE & PVC waste	Regional
Local PEC in surface water during emission episode (dissolved)	mg/L	3.38E-05	3.38E-05	5.61E-04	1.02E-03	8.00E-04	9.66E-05	3.38E-05
Local PEC in fresh-water sediment during emission episode	mg/kg ww	4.33E-01	4.33E-01	7.18E+00	1.31E+01	1.02E+01	1.24E+00	8.64E-01
Local PEC in seawater during emission episode (dissolved)	mg/L	4.56E-06	4.56E-06	5.84E-04	1.09E-03	8.23E-05	1.20E-05	4.56E-06
Local PEC in agric. soil (total) averaged over 180 days	mg/kg ww	1.09E-01	1.22E-01	3.77E+00	6.96E+00	2.16E-01	2.16E-01	8.72E-01
Daily human dose through water and food	mg/kg day	5.35E-03	2.50E-02	1.56E-01	2.54E-01	1.13E-02	8.37E-03	3.00E-02
Concentration in fish for secondary poisoning (freshwater)	mg/kg food	1.41E-01	1.41E-01	8.02E-01	1.38E+00	1.80E+00	3.36E-01	-
Concentration in fish for secondary poisoning (Marine)	mg/kg food	1.90E-02	1.90E-02	7.46E-01	1.38E+00	1.90E-01	4.34E-02	-
Concentration in prey for secondary poisoning of fish-eating marine top predators	mg/kg food	3.79E-02	3.79E-02	3.29E-01	5.83E-01	1.37E-01	7.80E-02	-
Concentration in earthworms from agricultural soil	mg/kg food	5.14E+00	5.20E+00	2.43E+01	4.10E+01	1.03E+01	1.03E+01	-

6.2.2 Monitoring data

Limited information with specific relevance to waste management appears to be available. In a study in China, mean levels of SCCPs and MCCPs in surface particulates ranged from 30,000–61,000, and 170,000–890,000 ng/g dry weight (dw), respectively for four e-waste recycling sites (Zeng, et al., 2016). In another study in China, a mean level of 21,000 ng/g MCCP in pond sediments was measured in an e-waste recycling site (Chen, et al., 2011).

In Norway for sediments of six landfills published in 2002, MCCPs were found in two landfill sediments in concentration levels of 2.7 to 11.4 mg/kg (Danish EPA, 2014). A Canadian study has indicated that leaching of MCCPs from landfills is likely to be negligible because of its strong bonding to soils (Environment Canada, 2008).

In the incineration of MCCPs, chlorine from the MCCP can possibly be identified in several waste streams (PE Eurore, 2010).

There are several data sources presenting measured values of MCCPs in the environment more generally but these are not replicated here in full. A summary is presented in **Figure 3**.

Levels in environmental compartments		
Surface water (UK) ^{a)}	< 0,62 – 3,75	µg/L
Sediment (UK)	>5	mg/kg wet weight
Levels in biota (selection)		
Mussels ^{a)}	100 - 12 000	µg/kg
Grey seal (liver and blubber) ^{a)}	40 - 100	µg/kg
Heron (liver) ^{a)}	100 - 1 200	µg/kg wet weight
Sheep liver (close to chlorinated paraffin production plant) ^{a)}	200	µg/kg
Rabbit muscle ^{b)}	2 900	µg/kg lipid
Moose muscle ^{b)}	4 400	µg/kg lipid
Fin whale ^{c)}	144	µg/kg (fat weight basis)
Cow's milk (UK) ^{c)}	63	µg/kg lipid
Beluga whale (blubber) ^{c)}	15 800 – 80 000	µg/kg wet weight
Levels in humans		
Human breast milk (UK) ^{c)}	6,2 - 320	µg/kg lipid

Figure 3: Measured values of chlorinated paraffins in environmental compartments, biota and humans
Source: ECB (2005)

- a) Combined short- and medium-chain chlorinated paraffins (C10-20);
b) Chlorinated paraffins (unspecified chain length); and
c) Medium-chain chlorinated paraffins (C14-17)

It is worth noting that the regional and local exposure estimates for surface water presented above (**Table 29** and **Table 30**) are generally lower than measured values shown in **Figure 3**. On the other hand, for sediment, whilst the regional and several of the local values estimated by the EUSES software are below 5 mg/kg wet weight (ww), some local PEC values do exceed the 5 mg/kg wet weight threshold shown in **Figure 3** (the values for the local PEC in fresh-water sediment during emission episode are 7.18 mg/kg ww for formulating PVC using recycle and 6.3 mg/kg ww for landfilling of WEEE; of the two the former figure is considered more robust).

Some additional recent data are available and are provided here by way of an update to the existing database of results⁴⁸:

- **MCCPs in sediments:** sediment samples (0–5 cm) were collected from 13 locations in the middle reaches of the Yangtze River in China. The Yangtze River is the longest river in Asia. Dozens of electronics factories, petrochemical plants and chlorinated paraffin manufacturers located at 13 towns in the province of Hubei have been regarded as potential emission sources of chlorinated paraffins. The concentrations of SCCPs in the sediment samples ranged from 4.19 to 41.6 ng/g dw, and the range for the chlorine contents was 61.8–63.8%. The MCCP concentrations ranged from not detected (n.d.) to 14.6 ng/g dw, and the chlorine contents of MCCPs were 55.2–59.9%. The researchers could not identify the exact sources of MCCPs in the sediments, although for SCCPs some informed assumptions could be made (Qiao, et al., 2016).

The same study team undertook similar research at the Yellow River in China. Thirteen surface sediment samples (0–5 cm deep) were collected from the middle reaches of the Yellow River. SCCP concentrations in the sediment samples ranged from 11.6 to 9.76×10^3 ng/g dw, and the chlorine contents of SCCPs were calculated to be in the range of 61.9–62.9%. The MCCP concentrations were in the range of 8.33–168 ng/g dw. The chlorine contents of MCCPs in all of the sediment samples were 57.1–59.9%. The MCCP concentrations in sampling sites tended to decrease with distance away from cities (Qiao, et al., 2016b). In another paper by the same team, again on samples collected from the Yellow River, the total SCCP concentrations in the sediment samples were 66–490.8 ng/g dw, and the total MCCP concentrations were 20.5–93.7 ng/g dw (Xia, et al., 2016).

A newly published study (Yuan, 2017) presents historical trends (1930s – 2010s) of SCCPs, MCCPs, and LCCPs in three Swedish sediment cores near a metropolitan sewage treatment plant (Himmerfjärden/ Södertälje), a wood-related industrial area (Rundvik/Umeå), and a steel factory (Nyköping), respectively. The temporal trends agree with the Swedish Chemicals Agency's statistics on chlorinated paraffin importation in Sweden or local industrial activities. A wide range of chlorinated paraffins from C8 to C36 remained intact in the sediments over the past 50 – 80 years, suggesting their persistence.

- **MCCPs in biota:** a study in the Yangtze River Delta in China has revealed the presence of chlorinated paraffins in several terrestrial species and birds of prey. The snakes showed the highest concentrations of chlorinated paraffins (200–340 µg/g lipid weight (lw), i.e. as high as 0.2–0.3‰ in extracted fat, followed with chlorinated paraffin levels of 97 µg/g lw in the toad and in the falcon, 8–130 µg/g lw. Among all quantified halogenated compounds, chlorinated paraffins were by far the most abundant contaminant, contributing over 90% of the total organohalogen contaminants in snake, toad, falcon, respectively. Concentrations of chlorinated paraffins were higher in terrestrial species (the falcon, snake and toad (8–340 µg/g lw)) than in the species relating to the aquatic environment (heron, eel and frog < LOD to 9.3 µg/g lw) (Zhou, et al., 2016).

More recently, six species of amphibians, fish and birds were sampled from paddy fields in the Yangtze River Delta in China and were screened for organohalogen contaminants. High concentrations of chlorinated paraffins were found in the snake, Short-tailed mamushi (range of 200–340 µg/g lw), Peregrine falcon (8–59 µg/g lw) and Asiatic toad (97 µg/g lw) (Zhou, et al., 2016). The findings of the recent study in China (Zhou, et al., 2016) (undertaken as part of a collaboration between Tongji University (Shanghai, China) and Stockholm University (Sweden)) confirm the importance of the terrestrial food chain to secondary poisoning.

⁴⁸ Copies of journal articles in press and results of unpublished information by Chinese scientists were kindly submitted by Dr Lirong Gao of the Chinese State Key Laboratory of Environmental Chemistry and Ecotoxicology of Beijing to whom the study team is grateful.

The aforementioned study at the Yellow River also included the testing of five fish samples were collected in Bohai Bay into which the Yellow River flows. The SCCP concentrations in the five fish samples were 373.6–3997 ng/g dw, and the MCCP concentrations were 42.1–5307 ng/g dw (Xia, et al., 2016);

- **MCCPs in human breast milk:** an analysis of chlorinated paraffins in pooled Swedish breast milk from 1996-2010 show a mean level for MCCPs of 14 ng/g fat weight and a maximum level of 30 ng/g fat weight (Danish EPA, 2014).

Measurements of SCCPs and MCCPs in human breast milk have also been undertaken in China, in 1,370 urban samples from 12 provinces in 2007 and 16 provinces in 2011 (Xia, et al., 2016b). SCCPs concentrations were found to be considerably higher than MCCPs when twenty-eight pooled samples were analysed for 48 SCCP and MCCP congener groups using the GC×GC-ECNI-HRTOFMS method. Total SCCP concentrations measured in 2007 ranged from 170 ng/g lipid (in Sichuan Province) to 6,150 ng/g lipid (in Hebei Province), with a median value of 681 ng/g lipid. MCCP concentrations were between 18.7 ng/g lipid (in Sichuan Province) and 350 ng/g lipid (in Hebei Province), with median of 60.4 ng/g lipid. In 2011, the median SCCP concentration was 733 ng/g lipid, and values ranged from 131 ng/g lipid (in Neimenggu Province) to 16,100 ng/g lipid (in Hebei Province). MCCP concentrations were in the range of 22.3 ng/g lipid (in Neimenggu Province) and 1,501 ng/g lipid (in Hebei Province), with a median value of 64.3 ng/g lipid. The levels of chlorinated paraffins increased from 2007 to 2011, which indicates that chlorinated paraffin production and use may be an important source of exposure. Within MCCPs, the C₁₄ congener showed by far the highest relative abundance in the samples collected accounting for approximately 70% of total MCCPs (Xia, et al., 2016b).

7 Impact and risk evaluation

7.1 Impacts on WEEE management as specified by Article 6(1) a

To the extent allowed by the limited information available, the presence of MCCPs does not have a discernible impact on EEE waste management operations, including on the possibilities for preparing for the reuse of WEEE or for recycling of materials from WEEE. It is known that PVC cable waste is increasingly being recycled, as confirmed by VinylPlus' statistics (106 ktonnes in 2015)⁴⁹. PVC cable waste is recycled into new articles, typically of low value. It is also reiterated that cables that may contain MCCPs and constitute components of larger EEE do not fall under the remit of the recast WEEE Directive.

On the other hand, as will be shown below, the use of MCCPs in the manufacture of PVC cables for use in EEE may result in unacceptable risks to the environment and (to a lesser extent) workers' health. Under the conservative assumptions made in Sections 5 and 6 of this report, some Risk Characterisation Ratios (RCR) may exceed 1 for some of the relevant operations (formulation, conversion of PVC and landfill of WEEE and PVC waste).

Since MCCPs are classified as *Aquatic acute 1; Very toxic to aquatic life and Aquatic chronic 1; Very toxic to aquatic life with long lasting effects*, they are also classified under the Seveso III Directive in the E1 hazard category. This means that the qualifying quantity (tonnes) of MCCPs as referred to in Article 3(10) of the Directive is 100 tonnes for lower-tier requirements and 200 tonnes for upper-tier requirements. It can be envisaged that large masterbatch or cable manufacturers might need to comply with the Seveso III Directive as far as the storage of MCCPs is concerned.

Section 8 of this document discusses the availability and feasibility of alternatives for MCCPs. Among the identified alternatives, substances with a more benign hazard profile can be identified.

7.2 Risks for workers

In order to carry out risk evaluation for workers, the estimated exposure has to be compared to a DNEL value to derive a Risk Characterisation Ratio (RCR). If the exposure is lower than the DNEL (RCR < 1), it is assumed that risks are controlled. If not, the risks are not controlled and additional RMMs (risk management measures) are required.

The risk characterisation performed below is based on the most conservative value, the EU RAR DNEL for carcinogenicity of 1.6 mg/m³ but commentary is also provided in relation to the EU RAR DNEL for lactation effects of 3.0 mg/m³.

The results of risk characterisation are presented in **Table 45** in Annex I.

It can be observed that the only two cases where the risks appear not to be controlled are during shredding of PVC cable waste (PROC24c – by inhalation), where the inhalation RCR for kidney carcinogenicity, as identified in the EU RAR, is 1.8, and during the conversion of PVC recyclate (PROC6 – RCR=1.4 by dermal exposure during calendaring operations where higher than ambient temperatures are used). It must be noted, however, that no respiratory protection equipment or gloves were considered during the assessment as it is understood that

⁴⁹ VinylPlus website, available at: <http://www.vinylplus.eu/progress/annual-progress/2013-2> (accessed on 1 August 2016).

these are not used uniformly. Of note is that the EU RAR did not identify an unacceptable risk to workers' health under all PVC-related scenarios examined (formulation/manufacture, calendaring, compounding, extrusion/moulding)

If the lactation DNEL is used, however, no risk for the workers is identified. On the other hand, if less rigorous risk management measures than those assumed (e.g. the presence of local exhaust ventilation (LEV) when recycling PVC waste has been assumed) are applied during recycling processes, it is likely that the risks through inhalation exposure would not be adequately controlled. Risks from dermal exposure seem to be adequately controlled and even if no gloves were used, the RCR would still be below 1.

7.3 Risks for the consumers

Consumer risks are not of relevance in this context. The EU RAR noted that consumer exposure to MCCPs in plastics is negligible.

7.4 Risks for humans exposed via the environment

The EU RAR did not identify any concerns for humans exposed via the environment (water, food and air). In this risk assessment using the oral DNEL of 0.115 mg/kg/day (see section 3.2.2) concern (RCR>1) was identified for the two scenarios formulating and conversion of PVC see **Table 31**. However, according to the addendum of the environmental EU RAR (2007), the TGD (Technical Guidance Document) default method used in this restriction proposal may substantially overestimate the concentrations of MCCP in root crops and thereby overestimate the daily human exposure via environmental routes.

Table 31: Risk characterisation ratios for man via the environment using the oral DNEL of 0.115 mg/kg/day derived in section 3.2.2.

Shredding WEEE	Shredding PVC	Formulating PVC	Conversion PVC	Landfill WEEE & PVC waste	Incineration WEEE & PVC waste	Regional
0.05	0.22	1.36	2.21	0.1	0.08	0.26

7.5 Risks for the environment

The results of the environmental exposure assessment will be compared to the PNECs that were calculated in the EU RAR, as presented in **Table 13**. The results of the comparison are shown in **Table 32**.

As can be seen in the table, some RCRs for PVC formulation and conversion, as well as two RCR values for landfilling of WEEE and PVC waste and one RCR value for incineration of WEEE and PVC waste are above 1, indicating a risk.

The results above must be considered with care for a number of reasons:

- Assumptions made in the modelling are generally conservative. However, since 40-45 % of the use of MCCP are outside of the scope of the restriction proposal and therefore are excluded in the exposure assessment, this will result in underestimations of some of the calculated RCRs;
- Releases from incineration could realistically be considered to be very low on the assumption of a high incineration temperature used and appropriate RMMs being in place. The RCR above 1 for the earthworm food chain could in reality be considered to be much lower
- For landfilling of MCCP-containing WEEE and PVC waste the RCRs for the fresh water sediment and the the earthworm food chain are higher than 1. Releases from landfilling could realistically be considered very low for well operated landfills. However, on the assumption that all landfills are not well operated the RCRs for the fresh water sediment and the the earthworm food chain might raise concern.
- There is large uncertainty as far as the MCCP quantities involved are concerned, as well as because of the variability of the congeners of MCCPs; and
- When taken into account the amount of WEEE waste exported to third countries (see section 5.3.1) we assume that there might be a risk for the environment in those countries but that has not been quantified in this report.

Table 32: Risk characterisation for local and regional environmental exposure as estimated by EUSES

Risk Characterisation Ratio	PNEC value	Shredding WEEE	Shredding PVC	Formulating PVC	Conversion PVC	Landfill WEEE & PVC waste	Incineration WEEE & PVC waste	Regional values
PEC/PNEC _{water} (freshwater)	1 µg/l	0.034	0.034	0.561	1.020	0.8	0.097	0.034
PEC/PNEC _{sediment}	5 mg/kg wet wt.	0.087	0.087	1.436	2.620	2.048	0.247	0.173
PEC/PNEC _{marine}	0.2 µg/l	0.023	0.023	2.920	5.450	0.412	0.06	0.023
PEC/PNEC _{soil}	10.6 mg/kg ww	0.010	0.012	0.356	0.657	0.02	0.02	0.082
PEC/PNEC _{oral} (sec poisoning – freshwater fish)	10 mg/kg food	0.014	0.014	0.080	0.138	0.18	0.034	-
PEC/PNEC _{oral} (sec poisoning – marine fish)	10 mg/kg food	0.002	0.002	0.075	0.138	0.019	0.004	-
PEC/PNEC _{oral} (sec poisoning – marine fish top predators)	10 mg/kg food	0.004	0.004	0.033	0.058	0.014	0.008	-
PEC/PNEC _{oral} (sec poisoning – agric. soil earthworms)	10 mg/kg food	0.514	0.520	2.430	4.100	1.026	1.026	-

At the regional level, no concern can be identified under the assumptions made. These results are generally consistent with the findings of the EU RAR which had identified unacceptable risks for the use of MCCPs in PVC compounding and conversion (surface water and sediment) but no unacceptable environmental risk at the regional level.

It must be noted that as per Article 3(5) of the RoHS2 Directive 2011/65/EU, “‘cables’ means all cables with a rated voltage of less than 250 volts that serve as a connection or an extension to connect EEE to the electrical outlet or to connect two or more EEE to each other”. In other words, only cables < 250 Volts individually put on the market (not together with EEE) are in the scope of the RoHS2 Directive. If it was assumed that a proportion of the consumed 15,000 t/y MCCPs was used in cables with a rated voltage of ≥ 250 Volts, a restriction on the use of MCCPs under the RoHS2 Directive would not eliminate the presence of MCCPs in cables placed on the EU market. However, there is no reliable information on what proportion of the MCCP tonnage may be present in such cables or indeed whether they are subject to the waste management processes described above.

8 Alternatives

8.1 Availability of alternative substances

When considering alternatives for MCCPs, it is important to reiterate their function as both secondary plasticisers⁵⁰ and flame retardants in PVC. MCCPs impart flame retardancy, improved water and chemical resistance, and better viscosity ageing stability together with a reduction in formulation cost (Danish EPA, 2014).

The key potential alternatives (and relevant in the context of PVC EEE) are presented in **Table 33** (Danish EPA, 2014, KemI 2015, UK CA 2008). The alternatives in the table is not equal one to one to MCCP. The table also presents the REACH registration status and technical feasibility aspects for the identified substances.

The main potential alternatives are considered to be long chain chlorinated paraffins (LCCPs), phthalates (e.g. DINP) and phosphate esters. LCCPs are suitable for some applications; phthalates are technically suitable where high fire resistance is not needed (although other additives, such as antimony trioxide can be used to impart these properties); whilst phosphate esters are generally technically suitable for applications where high fire resistance is required. Phosphate esters identified (in the UK 2008 report) include cresyl diphenyl phosphate (CDP), tricresyl phosphate (TCP), trixylyl phosphate (TXP), isopropylated triphenyl phosphate (IPP), 2-ethylhexyl diphenyl phosphate (ODP - octyl diphenyl phosphate) and isodecyl diphenyl phosphate (IDDP).

Alternatives in the KemI (2015) report for MCCPs when used as a plasticiser are other plasticisers include DINP, adipates and citrates as well as other plastic materials (discussed further below). Alternatives for MCCPs when used as a flame retardant identified in the KemI report include antimony trioxide and trialkyl phosphates.

When considering alternatives to MCCPs it is important to highlight that a ‘one size fits all’ alternative is unlikely to be available for a multitude of reasons. For example, in pure availability terms a number of the substances discussed above have not been registered or have been registered only in small tonnages. Therefore, it is unlikely that potential alternatives, such as phosphate esters, would have the market availability to replace MCCPs immediately.

⁵⁰ MCCPs are deemed ‘secondary’ plasticisers because they have insufficient compatibility for use as a sole plasticiser in many applications. As highlighted in ECB (2005), primary plasticisers in PVC are used to increase the elongation properties and softness of the polymer. Secondary plasticisers, when used in combination with primary plasticisers, cause an enhancement of the plasticising effects and so are also known as extenders.

Table 33. Technical feasibility/registration information for potential, not equal one to one alternatives (Danish EPA, 2014, KemI 2015, UK CA 2008, ECHA (2014b))

Substance name	CAS Number	Plasticiser	Flame retardant	Registered tonnage (t/y)	No of active registrants	Comments
Medium-chain chlorinated paraffins (MCCPs)	85535-85-9	Yes	Yes	10 000-100 000	12	-
Long-chain chlorinated paraffins (LCCPs)	63449-39-8	Yes	Yes, for high Cl content	10 000-100 000	7	-
Phthalates, e.g. DINP	28553-12-0	Yes	No	100 000-1 000 000	9	-
DIDP	68515-49-1	Yes	No	100 000-1 000 000	4	-
Adipates, e.g. DEHA	103-23-1	Yes	No	1 000-10 000	4	Low registered tonnage
Citrate, e.g. Acetyl tri-n-butylcitrate (ATBC)	77-90-7	Yes	No	100-1 000	1	Two different joint submissions of the substance. The smallest one dealing with textiles and polymers only
				10 000-100 000	5	
Trimellitates, e.g. Tris(2-ethylhexyl) trimellitate (TOTM)	3319-31-1	Yes	No	10 000-100 000	7	High aggregated tonnage, which is expected to increase in the future given that the substance has been highlighted as a substitute to a number of phthalates under regulatory pressure.-
Phosphates, e.g. Cresyl diphenyl phosphate	26444-49-5	Yes	Yes	-	-	Substance not registered
Tricresyl phosphate	1330-78-5	Yes	Yes	-	-	Substance not registered
Trixylyl phosphate	25155-23-1	Yes	Yes	100-1,000	2	Low registered tonnage
Triphenyl phosphate	115-86-6	Yes	Yes	1,000-10,000	1	Low registered tonnage
Isodecyl diphenyl phosphate	29761-21-5	Yes	Yes	1,000-10,000	2	Low registered tonnage
2-ethylhexyl diphenyl phosphate	1241-94-7	Yes	Yes	1,000-10,000	1	Low registered tonnage. Registration by a single company only covers professional application of PUR
				1,000-10,000	2	

Aluminium hydroxide	21645-51-2	No	Yes	1 000 000 - 10 000 000	50	-
Antimony trioxide	1309-64-4	No	Yes	1	100-1,000	Usually used as a synergist in combination with halogenated flame retardants. Two different joint submissions of the substance. The smallest one dealing with textiles and polymers only
				30	> 10,000	

Furthermore, considering the use of MCCPs in wire and cable applications, another important factor relates to the highly variable technical requirements for end-products due to a wide variety of safety and performance standards (PINFA 2013). Such variable requirements for wire and cables mean that they require very specific formulation. It is clear that the use of alternatives is therefore likely to be associated with more specific, product-by-product reformulations, tailor-made in order to ensure optimised results for the desired end-products. Health and environmental impacts on these substances are further presented in **Section 8.3**.

Despite the need to ensure end-products have the optimal functionality in accordance with their uses, it is also important to reiterate that the role of MCCPs is not purely a technical one. In fact, UK CA (2008) highlights that for PVC cable manufacture, imparting additional flame retardancy to the PVC is not generally the main reason for use of MCCPs in most markets. Instead, MCCPs are used because they are relatively inexpensive secondary plasticisers.

The authors further highlight that in such cases substitution with phthalates or trimellitates would be feasible. However, where flame retardancy is an issue, the use of alternative substances to impart the necessary flame retardant properties is clearly a necessity.

8.2 Availability of alternative materials

The Danish EPA (2014) report also highlights that plasticised PVC with MCCPs may be replaced by alternative polymer/flame retardant systems. The authors cite a 2013 report by the Phosphorus, Inorganic and Nitrogen Flame Retardants Association (PINFA), which highlights how low-smoke free-of halogen (LSFOH) or halogen-free flame retardants (HFFR) polymer compounds can be used in many ways to produce cables without PVC.

The use of alternative polymer systems (polyethylene, polypropylene and fluoroplastics) is also identified by UK CA (2008). The authors note that the implications of the use of these materials is that they would also require the use of other additives (e.g. heat/UV stabilisers, flame retardants) some with unknown risk profiles. Alternative materials cited in the KemI (2015) report include polyethylene, polypropylene, ethylene vinyl acetate and other plastic materials.

Key information from the PINFA report with regard to selected polymers and corresponding flame retardants, their working function and main applications in cables is provided in **Table 34**, which further highlights the variety in formulations used for PVC cable compounds.

Table 34. Selected HFFR cable compounds and most important end applications

Selected HFFR cable compounds and most important end applications			
Flame retardant	Working function	Polymers/compounds	Main Applications
Aluminium trihydroxide (ATH) Magnesium dihydroxide (MDH) Aluminium oxide-hydroxide (AOH, boehmite) Zinc borates Zinc hydroxystannates	In case of a fire, these mineral flame retardants decompose: - Absorbing energy; - Releasing water (thus reducing fire intensity and diluting fire gases); and - Creating an oxide fire barrier against heat from the flame and to prevent burnable polymer decomposition products from reaching the flame Zinc Borate is a smoke suppressant that works in the condensed phase by forming a glass-like char. Zinc Hydroxystannate works both in the gas phase (flame) and in the condensed phase (smoke) simultaneously	Polyolefins - Low-density polyethylene (LDPE) - Polyethylene vinyl acetate copolymer (EVA) - Polyethylen-co-butene - Polyethylen-co-octene Elastomers - Natural Rubber (NR) - Poly-ethylene-Diene Rubbers (EPDM) - Poly-Styrene-Butadiene Rubbers (SBR) - Silicone rubbers (SiR) Thermoplastic Elastomers (TPE)	Electrical cables - Low voltage - Medium voltage - Photovoltaic (PV) cables - Emergency lighting Control cables - Fire alarm cables Information cables - LAN cables - Telephone cables
Phosphorus flame retardants Phosphate esters (e.g. tricresyl phosphate (TCP)) Intumescent products based on: ammonium polyphosphates (APP), Polyphosphonates, metal phosphinates, aryl phosphates Melamine Derivatives Red phosphorus	Flame inhibition and charring properties of phosphorus based materials reduce the flammability of polymers. A char on the surface prevents heat transfer and protects the polymer below	Used in fire-resistant coatings for cables - Polyolefins - Polypropylene (PP) Elastomers - Thermoplastic Elastomers (TPE) - Thermoplastic Poly Urethanes - Thermoplastic Polyesters	Electrical cables - Photovoltaic (PV) cables Control cables - Lift cables - Fire alarm cables
Source: PINFA (2013)			

8.3 Hazardous properties of alternatives

Table 35 provides a summary of the most relevant concerns of selected alternatives used in EEE. The alternatives in the table is not equal one to one to MCCP. A number of these substances have been subject to recent authoritative reviews. As such, a brief summary has been provided with reference to the relevant reports for LCCPs.

LCCPs: LCCPs have shown low toxicity in oral doses from 4,000-50,000 mg/kg in rats. Data of studies of repeated oral toxicity studies in rats resulted in a LOAEL of 100mg/kg/day for the C₂₀₋₃₀ LCCPs. Based on data from MCCPs, a respective NOAEL of 23 mg/kg per day (equivalent to 300 mg/kg food) has been recommended.

LCCPs can cause slight eye irritation and could cause skin sensitisation reactions based on studies performed on guinea pigs. There are no reported toxicity studies on humans (Brooke, et al., 2009). US EPA (2015) have undertaken a risk assessment on LCCPs indicating that there are low risks to human health, however they may present “an unreasonable risk” following acute and chronic exposures to aquatic organisms. At least some congener groups present in and LCCP products are persistent to very persistent and bioaccumulative to very bioaccumulative. Notably, the results of the analysis undertaken for the Environment Agency were somewhat different: whilst, LCCPs were found to meet the P or vP (very persistent) criteria, they were believed to be unlikely to meet the B or vB (very bioaccumulative) criteria and thus could not be considered as PBT or vPvB substances (Brooke, et al., 2009).

Overall, whilst the lack of a harmonised classification would suggest that LCCPs are potentially of lower toxicity to MCCPs, environmental hazards might be similar to those of MCCPs, but available assessments do not necessarily agree on the bioaccumulation criterion.

Table 35: Summary of most relevant hazard concerns for identified alternatives (not one to one alternatives to MCCP)

Substance name	CAS Number	Human health concerns	Environmental health concerns	Harmonised (HC) classification	Source / additional information
Long chain chlorinated paraffins (LCCPs)	63449-39-8	Low toxicity	Potentially persistent and bioaccumulative (but past assessments reach different conclusions)	No classification	-
DINP	68515-48-0/28553-12-0	Significant increases of incidence of spongiosis hepatitis together with other signs of hepatotoxicity in rats. Disagreement regarding relevance of spongiosis hepatitis in humans. Concerns over endocrine disruption potential (anti-androgenic effects)	No toxic effects towards fish, invertebrates or algae	No classification Proposal not to classify for reproductive toxicity ⁵¹ Use of DINP in toys and childcare articles which can be placed in the mouth is restricted, entry 52 in Annex XVII, REACH.	Umweltbundesamt (2014) Echa (2018)
DIDP	68515-49-1 / 26761-40-0	Significant increases of incidence of spongiosis hepatitis together with other signs of hepatotoxicity in rats. Disagreement regarding relevance of spongiosis hepatitis in humans. Reprotoxic effects. Decrease in survival incidences (NOAEL: 33 mg/kg bw/day)	Low bioaccumulation properties	No classification Use of DIDP in toys and childcare articles which can be placed in the mouth is restricted, entry 52 in Annex XVII, REACH.	Umweltbundesamt (2014)
DEHA	103-23-1	DEHA was added to the CoRAP list in 2013 and is to be evaluated by the Finnish Safety and Chemicals Agency (Tukes) in	Tukes (2013) ECHA (2017) Environment Canada/ Health Canada (2011)	No classification	

⁵¹ Opinion of the Committee for Risk Assessment available online at ECHA's website:

https://echa.europa.eu/documents/10162/23821863/nr_annex_rac_seac_march.pdf/fcc9fe3c-1221-93ad-0fe0-e5772436e97c, accessed on 18 April 2017

		2018. DEHA has been suspected of having effects on the male reproductive system because it shares similarities in chemical structure and metabolism with DEHP			
Citrates e.g. Acetyl tri-n-butylcitrate (ATBC)	77-90-7	Low acute toxicity, low or slight sensitising, no mutagenic activity and no reproductive effects	Readily biodegradable as well as ultimately biodegradable. Indications for bioaccumulation potential and potential for aquatic toxicity	No classification	ECHA (2012)
Trimellitates e.g. Tris-2-ethylhexyl (TOTM)	3319-31-1	Added to CoPAR list 2012. None cited (negative results for reproductive toxicity, genotoxicity and carcinogenicity)	Potential PBT/vPvB	No classification	ECHA (2014b)
Aluminium hydroxide	21645-51-2	No risk to human health	Datagap concerning environmental hazards	No classification	Arcadis & EBRC (2011)
Cresyl diphenyl phosphate	26444-49-5	Chronic toxicant with effects on liver, kidney and blood. Effects on fertility	Readily biodegradable; toxic to aquatic organisms	No classification	Arcadis & EBRC (2011) KEMI (2015)
Tricresyl phosphate	1330-78-5	Inconclusive	Inconclusive	No classification	Arcadis & EBRC (2011)
Trixylyl phosphate	25155-23-1	On the Candidate List of Substances of Very High Concern for Authorisation, REACH. Reproductive toxicant	-	Repr. cat. 1B, thus no suitable alternative for MCCPs.	ECHA (2013)
Triphenyl phosphate	115-86-6	Chronic toxicant with effects on liver	Readily biodegradable, toxic to aquatic organisms	No classification	Arcadis & EBRC (2011) KEMI (2015)
Isodecyl diphenyl phosphate	29761-21-5	Risks identified	Does not meet the criteria for a PBT or vPvB substance, although several risks identified	No classification	Arcadis & EBRC (2011) Environment Agency (2009)

2-ethylhexyl diphenyl phosphate (ODP)	1241-94-7	Risks from consumer products not identified	No risk identified; not a PBT/vPvB ⁵²	No classification	Arcadis & EBRC (2011) ECHA website
Antimony trioxide	1309-64-4	Potential human carcinogen via inhalation and reproductive toxicant	Not readily biodegradable, low to moderate bioaccumulation potential	Carc. cat. 2, no suitable alternative for MCCPs	Umweltbundesamt (2014b) BAuA (2016) KemI (2015)

⁵² Details available at: https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact/-/substance-rev/8095/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=214-987-2&_viewsubstances_WAR_echarevsubstanceportlet_DISS=true (accessed on 22 August 2016).

8.4 Conclusion on alternatives to MCCPs

With regard to potential alternatives, the findings of this report are in line with that of the Danish EPA (2014). Alternatives such as LCCPs and plasticisers are commercially available (albeit in variable quantities), but there is an absence of evidence to support the suggestion that any single substance identified can substitute MCCPs across its uses in PVC cables. DINP and DIDP, for example, are PVC plasticisers that exhibit technical advantages compared to MCCPs (and have long been used as such), but they lack the combined plasticising and flame retarding effects of MCCPs and they are more costly.

With regard to alternative materials, it would appear that wires and cables containing MCCPs may be replaced by other polymers/flame retardant systems (incorporating halogen-free flame retardants or low-smoke free-of halogen polymer compounds) which can be used in a variety of ways.

Overall, it is clear that the use of alternatives is likely to be associated with more specific, product-by-product reformulations, tailor-made in order to ensure optimised results for end-products. One of the most pertinent issues in terms on substitution would appear to be that of cost, given the low price of MCCPs compared to the majority of potential alternatives.

Finally, whilst several potential alternatives with a more benign hazard profile can be identified, it should also be noted that some alternatives (such as antimony trioxide and trixylyl phosphate) have unfavourable (human health) hazard profiles, which would render them unsuitable as alternatives to MCCPs. LCCPs, the alternative most structurally similar to MCCPs, may appear to be less hazardous than MCCPs but still raise concerns over their environmental hazard profile (PBT properties).

9 Description of socio-economic impacts

9.1 Approach and assumptions

The socio-economic analysis is based on two scenarios:

- The “Baseline Scenario” is that the current legislation is not changed and MCCPs may continue to be used in EEE (in the context of this analysis, PVC-based cables); and
- The “Restriction Scenario”, under which the use of MCCPs in EEE relevant to the RoHS2 Directive is banned. Under that scenario, MCCPs would be replaced in PVC (and rubber, as appropriate) by a combination of alternatives such as LCCPs, DINP, and phosphate esters.

Key assumptions made in this analysis include:

- The selection of MCCPs or of the chosen alternative(s) does not have an effect on the lifetime of the EEE or its usability in its intended use;
- It is assumed that 15,000 t/y of MCCPs are placed on the market in the EU as part of EEE;
- Cables with a rated voltage of more than 250 Volts do not fall under the RoHS2 Directive. Although it is not known what percentage of MCCPs’ tonnage is actually used in such cables, it is possible that a proportion of current MCCP use would remain unaffected under the Restriction Scenario; and
- As discussed in Section 2.4.3, we assume that 59% of EEE consumed in the EU is manufactured in the EU with the remaining 41% being imported from outside the EU; and
- Our assumptions on the number of companies and workers of relevance to this analysis are presented in **Table 36**.

Table 36. Key assumptions on the number of companies and exposed workers

Supply chain stakeholder category	Number of EU companies	Number of potentially exposed workers	Sources and notes
MCCPs manufacturers	<12	Unknown - Not relevant to this analysis	There are 12 registrants. Of those, three appear to be Only Representatives. The EU RAR referred to 5 production sites
WEEE treatment installations (shredding)	450	2,250-6,750	(Umweltbundesamt, 2014) 5-15 workers per installation
PVC manufacturers	40 different plants spread over 21 sites	Total employment 7,000 – Not relevant to this analysis	(VinylPlus, 2016) These are only the ECVM members (5 in total) which represent 70% of the total European PVC market. Several other smaller companies exist
Masterbatch manufacturers	14	Unknown	EuMBC, available at: http://www.compounders.eu/members (accessed on 8 August 2016). EuMBC is an association representing more than 70% of the masterbatches and compounds manufactured in Europe (source: EuPC, https://echa.europa.eu/documents/10162/48252319-d727-42aa-8b3e-bb97cb218f0e (accessed on 26 August 2016)).
PVC cable manufacturers	235	Thousands (total of 65,000)	Europacable estimated that around 235 European companies would have to include RoHS specific aspects in the conformity

		workers across the EU cable industry)	declarations (bioIS & ERA Technology, 2012)
PVC waste recyclers (shredders)	52	250-780	The Recovinyl website ⁵³ identifies a total of 52 companies involved in PVC cable waste recycling in the EU. We assume 5-15 workers per company
PVC compounders	<50	<1,250	The amount of MCCPs estimated to be recycled with PVC is 1,200 t/y. At a 10% concentration, this is equivalent to 12,000 tonnes of PVC per year. The average annual capacity of plastics converters is 1,000 tonnes (based on 50,000 companies and ca. 45 million tonnes of production, according to the EuPC). To account for potentially small compounders, we assume that each compounder might process as low as 250 t/y. At that level, fewer 50 companies would be involved. We assume 25 workers per PVC compounder based on the Austrian Federal Environment Agency (Umweltbundesamt, 2014)

The geographical scope of the analysis below is the EEA, and primarily companies and consumers within the EU-28. There is no specific timeframe for the analysis; with the exception of some initial investments, the cost to industry would generally encompass the additional annual cost increase for raw materials as a result of the substitution of MCCPs by a more costly alternative plasticiser/flame retardant (or an alternative material). For the sole purpose of calculations, as far as the investment costs are concerned, these are annualised over a 5 year period at a discount rate of 4% (this time period is considered reasonable for a typical chemical company to assume a return on capital investment and is used in the absence of other information).

The following sections examine how different actors along the supply chain may be impacted by the introduction of the Restriction Scenario.

9.2 Impact on chemicals suppliers

9.2.1 Impact on MCCP manufacturers

Costs under the Restriction Scenario

Manufacturers of MCCPs currently sell an estimated 15,000 t/y MCCPs to manufacturers of PVC masterbatch and cables (again, we disregard here the use of MCCPs in rubber) which eventually find their way into the EU EEE market. Under the Restriction Scenario, the entirety of these sales could be lost, unless (a) MCCPs are used in PVC cables with a rated

⁵³ Recovinyl recyclers, available at: http://www.recovinyl.com/all-recyclers?field_cert_recylers_country2_tid=All&field_materials_tid=66 (accessed on 27 July 2016).

voltage higher than 250 Volts and thus fall outside the scope of the RoHS2 Directive, or (b) EEE that contains MCCPs could find alternative markets outside the EU.

In any case, inability to place EEE containing MCCPs on the EU market would lead to MCCP manufacturers suffering the loss of associated revenue and profits. Information on profit margins or indeed the market price of MCCPs is not available from consultation; information collected from the Internet (**Table 38**) suggests an average price of €850/t, meaning that the value of the affected market could be a maximum of $€850 \times 15,000 = \text{ca. } €12.8 \text{ million}$.

Benefits under the Restriction Scenario

LCCPs are among the potential alternatives for MCCPs. The REACH registrants for LCCPs include four companies that have also registered MCCPs (the number of MCCP registrants is twelve, as shown in Section 1.3.2). Therefore, if part of the current EU consumption of MCCPs was replaced by volumes of LCCPs, it could be envisaged that at least some of the MCCP manufacturers would be able to sell to their customers LCCPs as a substitute. These sales would moderate the loss of revenues associated with the losses of MCCP sales (as shown in **Table 38**, the price of LCCPs per tonne is estimated to be ca. 24% higher than MCCPs, or €1050 vs. €850 per tonne).

9.2.2 Impact on PVC manufacturers

Costs under the Restriction Scenario

It has been shown in Section 8.2 that alternative materials to PVC for cable insulation are available on the market. It is therefore a realistic possibility that if MCCPs were no longer available for use, the reformulation cost increase could lead certain cable manufacturers to consider alternative materials. This could mean that an unknown proportion of the volume of PVC currently sold for cable manufacture with MCCPs formulations would be lost. These impacts cannot be quantified with the information currently available. It is worth noting that the share of PVC in the EU cables market has been declining over many years.

Benefits under the Restriction Scenario

No benefits can be envisaged for PVC manufacturers. The European PVC plants are not manufacturing alternative materials such as polyethylene which might be used as replacements for PVC.

9.2.3 Impact on manufacturers of alternatives

Costs under the Restriction Scenario

No additional costs can be envisaged.

Benefits under the Restriction Scenario

Manufacturers of alternatives would benefit under the Restriction Scenario as they would be given the opportunity to sell products as replacements for MCCPs. Beyond LCCPs, there is a wide variety of choices that current users of MCCPs could make, both alternative substances (and combinations thereof) and alternative materials. However, it is difficult to quantify the benefits for these stakeholders for several reasons:

- There is no reliable information to guide us as to whether alternative substances or alternative materials would be the preferred substitution choice. The focus here unavoidably is on alternative substances because the quantitative information available on alternative materials is very limited;
- It is clear that MCCPs can only be replaced by a mix of alternatives, as there is no universal alternative for all applications of MCCPs. However, the composition of the mix cannot be predicted; and
- It is not clear as to what loading/substitution ratio would be required for each of the alternatives. Some information from literature can be used to make a series of assumptions. For example, Weil et al (2006) explained how a PVC formulation that contains MCCPs and a phthalate can be replaced by a combination of higher phthalate loading and higher antimony trioxide loading. Similarly, a PVC formulation that is based on MCCPs and a phosphate plasticiser can be replaced by a combination of a phthalate and a higher loading of the phosphate plasticiser.

Table 37 summarises the composition data presented in the box above. The table essentially shows how the loadings of additives in the PVC formulation would need to change for the performance of the formulation to remain largely the same. These figures can be used in making cost calculations later in this document, but it must be noted that these formulations primarily concern the fire-retarding properties of PVC.

Table 37. Example fire-retarded PVC formulations with or without MCCPs (all figures in phr (parts per hundred resin/rubber))

PVC additive	Formulation A	↔	Formulation A'	Formulation B	↔	Formulation B'
DINP*	42		53	-		16
Antimony trioxide	4		8	3		3
MCCPs	12		-	12		-
Calcium carbonate				30		30
2-ethylhexyl diphenyl phosphate				25		35
Source: Weil et al (2006)						
* The loading of DINP is assumed to be 1.06 times the loading of DOP (DEHP), as shown in Wilkes et al (2005)						

As antimony trioxide has a harmonised classification as Carc. cat. 2 it is not a suitable alternative for MCCPs. Therefore, Formulation B' will not be used in further socio-economic analysis.

Overall, the benefits for the manufacturers of the alternatives cannot be reliably quantified. However, it can be asserted that EU companies would be among the beneficiaries as most of the identified alternative substances have been registered under the REACH Regulation.

9.3 Impact on cable manufacturers

The widespread use of MCCPs has certainly been facilitated by the fact they are inexpensive and simple to produce. Indeed, several authoritative sources have highlighted that MCCPs are significantly cheaper than other plasticisers/flame retardants. For example, UK CA (2008) highlights that for PVC products the use of LCCPs is expected to result in a cost increase of 20-160% (dependent on formulation and end application) when compared to MCCPs. For the phthalates DINP and DIDP, this cost increase is expected to be in the region of 40-60% and it is highlighted that phosphate esters may result in up to four times the cost of MCCPs.

The report also provides insight into the additional costs for potential alternative materials, noting that the use of polyethylene, polypropylene, fluoroplastics (or other alternative plastic materials) is likely to make production costs by 50-200% higher (leading to 10-20% higher costs associated with the production of overall electrical insulation⁵⁴).

Beyond the above comparison, overall there is very little detailed comparative data available in the literature in order to assess the costs associated with using MCCPs and potential alternatives in PVC cables. For this reason, attempts have been made in the following table to provide a basic substance price comparison, utilising price quotes from an online marketplace. This information should serve as indicative only, however, it does appear consistent with the view that MCCPs are low cost when compared to a range of potential alternatives. Only aluminium hydroxide appears to be less costly than MCCPs.

Table 38. Cost comparison of MCCPs and potential alternative (not equal one to one) substances, in bold substances used in Table 37 and the calculation in Table 39

Substance	CAS Number	Average Price (€/t) (FOB*)	Notes	Observations
MCCP	85535-85-9	850	Based on 7 available prices from China/India	Highly variable purities available
Long-chain chlorinated paraffins (LCCPs)	63449-39-8	1050	Based on 10 available prices from China/South Africa	
DINP	28553-12-0	1650	Based on 10 available prices from China	Minimum purity 99.5%
DIDP	68515-49-1	2000	Based on 4 available prices from China	Minimum purity 99.5%
DEHA	103-23-1	1400	Based on 10 available prices from China	Minimum purity 99-99.5%
Citrates, e.g. Acetyl tri-n-butylcitrate (ATBC)	77-90-7	1600	Based on 8 available prices from China	Minimum purity 99-99.5%
Trimellitates e.g. Tris-2-ethylhexyl (TOTM)	3319-31-1	2050	Based on 8 available prices from China	Minimum purity 98-99.5%
Aluminium hydroxide	21645-51-2	600	Based on 10 available prices from China	Minimum purity ranges from 99 – 99.6%
Cresyl diphenyl phosphate	26444-49-5	2050	Based on 4 available prices from China	Minimum purity 99% (2 values not available)
Tricresyl phosphate	1330-78-5	3250	Based on 9 available prices from China	Minimum purity 99% (3 values not available)
Triphenyl phosphate	115-86-6	2500	Based on 6 available prices from China	Minimum purity 99-99.9%

⁵⁴ Based on UBA (2001) in UK CA (2008).

Isodecyl diphenyl phosphate	29761-21-5	3050	Based on 3 available prices from China	Minimum purity ranges from 99 – 99.8%
2-ethylhexyl diphenyl phosphate	1241-94-7	2450	Based on 1 available price from China	Minimum purity 99%
Source: https://www.alibaba.com/				
* Free on Board; values rounded to the nearest €50				

Substance costs are in reality just one element when comparing the prices of potential alternatives. Loading is also a factor of importance.

The potential replacement ratios for additional substances are also important to consider (e.g. if an alternative substance must be used in a higher quantity in order to achieve the same effect as MCCPs). Unfortunately, exact information in terms of MCCPs and alternatives loading capacities does not appear to be available.

Masterbatch and/or cable manufacturers will bear the main costs for the replacement of MCCPs by alternative plasticiser/flame retardants. As explained above, we disregard here the possibility of using an alternative insulation material and focus solely on the possibilities for replacing MCCPs by one or more alternative substances. We also assume that 15,000 tonnes of MCCPs are used by EU masterbatch/cable manufacturers. Part of this production may be placed on the market in non-EU markets but a largely equivalent quantity of masterbatch/cables containing MCCPs may be imported into the EU (see Fel! Hittar inte referenskölla.).

Three cost elements can be envisaged: the change in the cost of the plasticiser/flame retardant; the cost of process and equipment adaptations to the chosen alternative; and the cost of re-qualification of the new products. These costs are further discussed below.

Changes to the cost of the plasticiser/flame retardant

For the purposes of a single calculation, we assume that MCCPs would be replaced in equal parts (i.e., in each case, 7,500 t/y MCCPs) by LCCPs and a combination of DINP and 2-Ethylhexyl diphenyl phosphate. The calculation is presented in **Table 39** below.

Table 39: Calculations of the cost for an alternative with LCCP and one for the Formulation B' (-ethylhexyl diphenyl phosphate and DINP) compared to MCCPs.

Replacements substances	Shares in the formulation	Market price (€) ⁵⁵ see Table 38	Amount needed annually (tonnes/year)	Annual cost	Annual price difference (€/year)
MCCPs Baseline	-	850	7,500	850×7,500 = 6,375×10 ⁶	0
LCCPs	1:1	1,050/t (Table 38 and https://www.alibaba.com/)	7,500	1,050×7,500 = 7,875×10 ⁶	1.5 million

⁵⁵ Available at <https://www.alibaba.com/>.

2-ethylhexyl diphenyl phosphate and DINP	Formulations B and B' in Table 43: 12 phr (parts per hundred resin/rubber) of MCCPs would be replaced by an extra 10 phr 2-ethylhexyl diphenyl phosphate and 16 phr DINP	2-ethylhexyl diphenyl phosphate: 2,450 DINP: 1,650	2-ethylhexyl diphenyl phosphate: 10/12x7,500 =6,250 DINP: 16/12x7,500 =10,000	2,450x6,250 +1,650x10,000 = 31,8x10 ⁶	25,4 million
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The total increased annual cost per year for cable manufacturers when replacing half of the 15,000 tonnes of MCCP by LCCP and the other half with a combination of DINP and 2-Ethylhexyl diphenyl phosphate results in €27 million. However, the estimate €27 million/y might be too high an estimate, for a number of reasons:

- It might not be required that the entire consumption of MCCPs be replaced by alternative plasticisers/flame retardants (for example, the RoHS2 Directive does not apply to cables with a rated voltage of over 250 Volts); and
- If LCCPs were to be used more widely than what is assumed above, the overall cost increase would be lower.

Cost of process and equipment adaptations to the chosen alternative

There appears to be little information available on the equipment costs of MCCPs substitution. The recently published restriction proposal for four phthalates (see ECHA (2016)) highlights that many plasticisers, such as DINP and DIDP, can often replace DEHP without any major process or equipment modifications. As MCCPs have traditionally been used in association with DEHP (due to their good compatibility), this somewhat infers that major adaptations to process equipment would be unlikely, but more tangible evidence is required.

Information on the cost of the necessary process and equipment adaptation specific to MCCPs and PVC cables is not available. The RoHS restriction dossier submitted by the Austrian Federal Environment Agency on DEHP⁵⁶ (Umweltbundesamt, 2014) has used a basic calculation of these costs. The Agency assumed a ratio of material cost to investment cost of 85:15. If this is used here in the absence of information, the additional cost namely the investment cost would be €27 million × (15÷85) = €4.8 million, which would be split between EU based and non-EU based cable manufacturers. As noted earlier, we assume that thus cost would be spread over 5 years; with a discount rate of 4%, the annualised cost would be ca. €1.1 million.

Several of the alternatives identified in Section 8 are well-known substances and therefore, technically, the cost of process and equipment adaptations might not be significant, particularly if the large number of cable manufacturers is taken into account⁵⁷. Moreover, the use of MCCPs in the EU has been declining in recent years suggesting that substitution could be technically feasible. However, it is again noted that MCCPs have a dual role of

⁵⁶ The calculation made for DEHP is used here in the absence of other information. DEHP is also a plasticiser (a primary one), it is also used in flexible PVC and is also present in PVC cable formulations. On this basis, it is assumed that MCCPs and DEHP share some similarities in the present context.

⁵⁷ By way of example, if a PVC cable manufacturer used 1,000 t/y MCCPs, the increase in the cost of the plasticiser flame retardant would be at least €0.2 million (when moving to LCCPs) with a further €0.13 million in equipment costs.

(secondary) plasticiser and flame retardant which many of the alternatives cannot match. Therefore, reformulation could prove to be a demanding process.

It can be envisaged that cable manufacturers would aim to pass at least part of their costs to their customers.

Cost of re-qualification of reformulated products

With substitution comes the need to consider the additional costs associated with the development and approval of new products (e.g. re-qualification and re-certification). Cable performance is regulated under numerous national and international standards⁵⁸. Cable manufacturers would need to ensure that any reformulation of their PVC products to eliminate the use of MCCPs would not impact upon their products' ability to meet the relevant performance (and safety⁵⁹) standards. Of relevance in this context is the HAR system for the common marking for cables complying with harmonised European specifications. This enjoys a high reputation, making it a virtual standard on the European market⁶⁰. Cousins (2000) highlights that up to two years of testing may be required for the approval of medium and high voltage cables, indicating that this may be an important cost parameter to consider. No information is available that would allow us to describe and quantify this cost to cable manufacturers.

9.4 Impact on EEE manufacturers

The magnitude of costs of EEE manufacturers is difficult to estimate. Relevant cost elements might include (Economics Europe, 2015):

- **Technical costs:** these may include capital expenditure, R&D expenditure and operating expenditure; and
- **Compliance costs:** these include costs for ensuring compliance with the RoHS2 Directive, i.e. for ensuring that RoHS2-relevant components are MCCP-free as supplied by cable manufacturers.

With regard to technical costs, it may be assumed that any research in identifying the most suitable alternatives for MCCPs and reformulating PVC cable formulations as well as the actual change to alternatives to MCCPs would be undertaken by cable manufacturers and the cost would be passed on to EEE manufacturers. The part of this additional cost that can be quantified was found above to be €28.1 million/y for the first five years and €27 million/y

⁵⁸ See, for instance, a list of British standards relevant to cable manufacture here: <http://www.batt.co.uk/products/view/148/British-Cable-Standards> (accessed on 9 October 2016).

⁵⁹ See relevant EN (and IEC) standards on the fire performance of cables, namely standards EN 50266, 50267, 60332, 61034, at http://www.leoni-industrial-projects.com/fileadmin/bu/ip/pdf_-_Vortraege/Table_fire_behaviour.pdf (accessed on 9 October 2016).

⁶⁰ Cable manufacturers located in a country where European Committee for Electrotechnical Standardization (CENELEC) standards have been officially implemented can address themselves to a Certification Body member of HAR. The Certification Body will collect a number of product samples for testing. A positive conclusion of these tests will result in the licence to use the HAR Mark being granted to the manufacturer. To maintain the validity of the licence, a stringent programme of surveillance tests and assessments, carried out four times a year, is put in place. Types of cables within the scope of the HAR scheme can be found at <http://www.etics.org/page.php?p=204> while a list of national Certification Bodies is available at <http://www.etics.org/members.php?s=6> (accessed on 9 October 2016).

thereafter. It was explained above that, on one hand, the additional cost associated with the use of alternative substances might be an overestimate, but on the other hand, the cost of re-qualification and re-certification of MCCP-free PVC cables has not been possible to quantify and thus has been excluded from the calculations. On the basis of domestic production representing 59% of overall EEE consumption in the EU, it can be assumed that the economic burden on EU-based manufacturers of EEE would be at least €28.1 million \times 59% = €16.6 million/y over the first five years and €27 million \times 59% = €16 million/y thereafter, with the rest being borne by non-EU manufacturers of EEE⁶¹. Clearly these estimates are rough and depend on the relative market prices of alternatives which are likely to fluctuate in the future.

Compliance costs may partly be covered by the administrative costs described below and in any case for EEE manufacturers who have already complied with the RoHS Directive, compliance costs will be marginal (and will be shared between EU and non-EU enterprises).

To give some perspective of the magnitude of this cost, we assumed earlier that 15,000 tonnes of MCCPs (see Section 2.4.2) could be found within 9.1 million tonnes of EEE (see Section 5.3.1). Therefore, the total estimated cost (material cost of €27 million plus investment cost of €4.8 million according to section 9.3) of €31.8 million could be equivalent to €0.003 per kilogram of EEE (whether it is manufactured inside or outside the EU).

In conclusion, the overall cost increase would be very small in comparison to the actual size of the EEE market. It is worth noting that in the markets of consumer electronics manufacture and domestic appliance manufacture, ca. 80% of companies are not SMEs (Economics Europe, 2015).

9.5 Impact on EEE users

The cost on EEE users would be associated with the cost that EEE manufacturers would be prepared to pass on in the form of increased EEE retail prices. However, the amount per piece of equipment would be very small. For example, for a cooker weighing 60 kgs, using the figure of €0.003 per kg EEE calculated above, would produce an additional cost of €0.18. Another calculation can be made as follows:

- A (large) item of EEE contains 2 kg of PVC sheathing which contains MCCPs;
- A PVC cable contains 10% wt. MCCPs, thus the EEE article contains 0.2 kg of MCCPs;
- MCCPs are replaced by a combination of alternatives with a higher raw material cost. The cost increase is estimated at +€3,400/t or €3.4/kg⁶²;
- The additional cost for this item of EEE due to the replacement of MCCPs would be $0.2 \times €3.4 = €0.68$.

Either way, the likely cost increase for users of EEE in the EU would be very small.

⁶¹ EU manufacturers of EEE would probably replace MCCPs-containing PVC cabling in products exported outside the EU but the costs for this action are not considered here.

⁶² In an example provided earlier, 7,500 tonnes of MCCPs are replaced by a combination of DINP and 2-ethylhexyl diphenyl phosphate with an additional cost of €25.4 million. Therefore, the additional cost per tonne of MCCPs replaced is ca. €3,400.

9.6 Impact on waste management

The presence of MCCPs does not impact on the management of PVC cable waste at present and their substitutes would likely not impede the continued recycling or other end-of-life management of WEEE and PVC cable waste.

9.7 Impact on administration

An additional cost may be borne by EEE manufacturers, importers and the authorities for determining the presence of MCCPs in PVC cables (and rubber articles). However, detection and quantification of MCCPs could be difficult but still possible.

Methods previously used for the detection and quantification was either the high or low definition gas chromatography coupled to an electron capture negative ion mass spectrometry (GC-ECNI-MS) (Yuan, 2016). Although cost effective, it is difficult to accurately detect and quantify MCCPs using these methods.

However, recent development of expensive but advanced methods like the atmospheric pressure chemical ionization source operated in negative ion mode followed by quadrupole time-of-flight high-resolution mass spectrometry (APCI-qTOF-HRMS) (Bogdal, 2015) (Yuan, 2017) or the gas chromatography combined with a high resolution mass spectrometry allows for easier resolution of individual congeners distinction. The APCI-qTOF have the ability to accurately identify and measure different congeners by carbon chain length and chlorination level. The high resolution mass spectrometry allows for easier resolution osepation of individual congeners distinction.

The expensive nature of these state-of-the-art techniques may result to an unknown laboratory cost for sample analysis. Whilst the expenditure by EEE manufacturers, importers and authorities would translate into revenues for testing laboratories, an administrative burden would undoubtedly arise (the Austrian Federal Environment Agency has assumed for the EU as a whole 7,000 test per year (Umweltbundesamt, 2014)).

9.8 Human health and environmental impacts

9.8.1 Human health impacts

An overview of the impacts on human health under the Restriction Scenario is represented in **Table 40**.

Table 40: Summary of human health impacts along the supply chain under the Restriction scenario

Supply chain stakeholder category	Number of EU companies	Number of potentially exposed workers	Impacts on human health	Comments
MCCPs manufacturers	<9	Unknown	Unknown	An assessment of exposure and risk has not been undertaken in this report as the focus is on waste management of EEE. The EU RAR established that there was no unacceptable risk for workers involved in the manufacture of MCCPs
Alternatives manufacturers	Numerous	Unknown	Uncertain effect	An assessment of exposure and risk has not been undertaken in this report. Impacts on worker health from increased sales (and thus increased manufacture) of alternative substances will depend on operating conditions and RMMs and on the properties of the alternative substances (for instance, trixylyl phosphate and antimony trioxide have a harmonised classification, DEHA is under investigation for reprotoxic effects and phthalates cause effects in the liver, but other alternatives are more benign)
PVC manufacturers	40 different plants spread over 21 sites	7,000	Neutral	These workers are not exposed to MCCPs or alternatives
Masterbatch manufacturers	14	Unknown	Unknown	An assessment of exposure and risk has not been undertaken in this report as the focus is on waste management of EEE. The EU RAR established that there was no unacceptable risk for workers involved in the formulation of PVC. New risks may in theory arise for this group of workers as a result of the increased use of alternative substances with an unfavourable human health hazard profile
Cable manufacturers	235	Thousands	Unknown	An assessment of exposure and risk has not been undertaken in this report as the focus is on waste management of EEE. The EU RAR did not look into these operations
WEEE treatment installations (shredding)	450	2,250-6,750	Low benefit	Modelling undertaken for this report shows a maximum long-term inhalative exposure of workers of 1.40 mg/m ³ for PROC 24c (<i>High (mechanical) energy work-up of substances bound in materials and/or articles - pt > mp - High Fugacity</i> ; see Fel! Hittar inte referenskölla.). The risk characterisation has not raised any concern (see Fel! Hittar inte referenskölla.)

PVC waste recyclers (shredders)	52	250-780	Benefit	Modelling undertaken for this report shows a maximum long-term inhalative exposure of workers of 2.80 mg/m ³ (<i>High (mechanical) energy work-up of substances bound in materials and/or articles - pt > mp - High Fugacity</i> ; see Fel! Hittar inte referenskälla.). The risk characterisation has raised some concern over inhalation exposure (see Table 45). Actual risk will depend on RMMs and operating conditions. The EU RAR did not identify an unacceptable risk to workers' health under all PVC-related scenarios examined
PVC compounders	<50	<1,250	Benefit	Modelling undertaken for this report show a maximum local dermal exposure of workers of 1.2 mg/cm ² (calendering operations; see Table 44). The risk characterisation has raised some concern over inhalation exposure (see Table 45). Actual risk will depend on RMMs and operating conditions. The EU RAR did not identify an unacceptable risk to workers' health under all PVC-related scenarios examined
Landfills	8,400	Unknown	Unknown	No discernible exposure is expected. An assessment of exposure and risk has not been undertaken in this report
Incinerators	715	Unknown	Unknown	No discernible exposure is expected. An assessment of exposure and risk has not been undertaken in this report
Consumers/general public	-	500 million citizens	Unknown	An assessment of exposure and risk has not been undertaken in this report. The EU RAR established that there was no unacceptable risk for consumers or for humans exposed via the environment

The key conclusions are:

- Overall, there will be impacts on human (workers') health under the Restriction Scenario;
- However, benefits would generally be limited to the shredding of PVC cable waste and the compounding of PVC with MCCP-containing recycle. The calculated Risk Characterisation Ratios that give rise to concern are only marginally higher than 1;
- The key beneficiaries will be a group of an estimated max. 2,000 workers in the EU PVC industry; and
- In the absence of an Exposure-Risk relationship for MCCPs, it is not possible to monetise the benefits arising for workers under the Restriction Scenario.

9.8.2 Environmental impacts

An overview of the benefits to the environment under the Restriction Scenario is represented in **Table 41**. The key conclusions are:

- Overall, benefits to the environment would be focused on the elimination of releases of MCCPs during the shredding of waste (WEEE and PVC cable waste) and the formulation and compounding of PVC; and
- For well operated landfills and incinerators under the strict conditions prescribed by regulation, releases of MCCPs from the PVC matrix should be low. However, release from not well operated landfills and incinerators calculated through modelling cannot be neglected;
- The overall releases of MCCPs that would be eliminated would amount to 4-27 tonnes per year if taking into account emissions from not well operated landfills and incinerators; and
- Elimination of releases of MCCPs from these activities would also mean the elimination of releases of SCCPs which are to be found in imported commercial MCCPs products.

Table 41. Summary of environmental impacts along the supply chain under the Restriction scenario

Supply chain stakeholder category	Number of EU companies	Impacts on the environment	Comments
MCCPs manufacturers	<9	Unknown	Releases of MCCPs during their manufacture have not been quantified in this report. Assuming that a decreased demand for MCCPs might lead to decreased manufactured volumes, there might be a decrease in MCCPs releases to the environment. Note that the EU RAR did not identify an unacceptable risk to the environment for the production stage of MCCPs.
Alternatives manufacturers	Numerous	Uncertain effect	Potential increased release of alternatives during their manufacture. Some concerns over their hazards exist (see Table 35).
PVC manufacturers	40 different plants spread over 21 sites	Neutral	Potential increased release of alternatives during their manufacture of PVC.
Masterbatch manufacturers	14	Uncertain effect	Not explicitly assessed in this report. Expect similarities to PVC formulation (see below).
Cable manufacturers	235	Neutral	Not assessed in this report. Unlikely that any significant MCCPs emissions occur.
WEEE treatment installations (shredding)	450	Benefit	A decrease of 0,75 tonnes of MCCP to air. (Risk Characterisation Ratios calculated in this report do not show an unacceptable risk with MCCP. However, an estimated 0.75 tonnes of

			MCCPs are expected to be released to air each year see Table 26.)
PVC waste recyclers (shredders)	52	Benefit	A decrease of 1.09 tonnes of MCCP to air. (Risk Characterisation Ratios calculated in this report do not show an unacceptable risk. However, an estimated 1.09 tonnes of MCCPs are expected to be released to air each year see Table 26.)
PVC formulation	<50	Benefit	A decrease of 0.36 and 0.12 tonnes of MCCP to air and water. (Risk Characterisation Ratios calculated in this report show a concern for marine water and sediment. An estimated 0.36 and 0.12 tonnes of MCCPs are expected to be released to air and water respectively each year see Table 26.)
PVC conversion		Benefit	A decrease of 0.09 and 0.09 tonnes of MCCP to air and water. (Risk Characterisation Ratios calculated in this report show a concern for freshwater, marine water and sediment. However, an estimated 0.9 and 0.9 tonnes of MCCPs are expected to be released to air and water respectively each year see Table 26.)
Landfills	8,400	Neutral - Benefit	A decrease of 0 to 6.2 and 0 to 21.1 tonnes of MCCP to air and water. Under normal operating conditions, releases of MCCPs to the environment should be adequately controlled. However, in the opposite situation there might be release of MCCPs to the environment and therefore a benefit. (Modelling results suggest that 6.2 tonnes of MCCPs are released to air and 21.1 tonnes are released to water each year see Table 26.)
Incinerators	715	Neutral	No benefit in the restriction scenario. (Under normal operating conditions, releases of MCCPs to the environment should be adequately controlled. Modelling results suggest that 0.12 tonnes of MCCPs are released to air and 0.06 tonnes are released to water each year see Table 26.)

9.9 Distributional effects

No significant social impacts are expected. The reduction in demand for MCCPs might lead to a reduction in employment among manufacturers of MCCPs but, on the other hand, the increase in demand for alternatives would counterbalance any such job losses. Elsewhere along the supply chain, no real impact is expected.

9.10 Total socio-economic impact

The above socio-economic costs from a restriction on the use of MCCPs are compared to the benefits to human health and the environment in **Table 42**. The overall quantifiable costs are €8.1 million per year over the first five years and €7 million/y thereafter, but it should be noted that some cost elements have not been possible to monetise (e.g. the cost of re-qualification and re-certification of MCCP-free cables). These costs could translate into a cost increase of €0.003 per kilogram of EEE or less than €1 for a single large appliance sold to the consumer. Clearly, the day-to-day fluctuations in currency exchange rates and the prices of raw materials are far more important than this cost. The cost estimates for year 6 and thereafter should be taken with great care. The conditions on the market cannot be predicted with such a long time horizon, making the estimates very uncertain.

On the other hand, worker exposures to MCCPs will be eliminated along the supply chain and a total of 4.12 tonnes of MCCPs per year would no longer be released to air and water. A simple calculation would indicate that the annual cost of the proposed restriction after year 5 would be €7 million ÷ 4.12 tonnes = ca. €1,600 per kilogram of MCCPs released (without discounting). An illustration of the different costs and benefits identified is provided in **Table 42** below.

Table 42: Illustration of socio-economic costs and benefits for human health and the environment from a restriction on the use of MCCPs.

Supply chain link	Description	Costs		Human health and environmental benefits		Difference between Restrictions and Baseline Scenarios (comparison of costs and benefits)
		Value		Human health benefits	Environmental benefits	
MCCPs manufacturers	Loss of sales of MCCPs but potentially gain of new sales of LCCPs	Up to €12.8 million/y (probably less)		Low benefit to workers (EU RAR identified no concern)	Low benefit to environment (EU RAR identified no concern)	Overall economic costs of at least €31.8 million/y shared spread between cable manufacturers, EEE manufacturers (EU & non-EU) and consumers. Overall human health and environmental benefits include lower worker exposures and avoidance of the release of 4.12 tonnes of MCCPs per year
PVC manufacturers	PVC may be replaced by other polymers in cable formulations	Not quantified		No changes	No changes	
Alternatives manufacturers	Generation of income from new sales of alternatives	Unknown but it would at least balance the losses of MCCPs manufacturers and PVC manufacturers		There are some alternatives which are better than MCCP. Other alternatives raise health concerns see Table 35	There are some alternatives which are better than MCCP. Other alternatives raise concerns over PBT properties see Table 35	
Masterbatch manufacturers/ Cable manufacturers	Loss of profit from increased cost of plasticiser/flame retardant. Cost of process and equipment adaptation	€4-8 million investment costs €27 million/y for alternatives		Not assessed in this report. Any exposure to MCCPs might be replaced by exposure to alternatives	Not assessed in this report. Any releases of MCCPs might be replaced by releases of alternatives	
EEE manufacturers	Loss of profit from higher cost of MCCP-free PVC cabling. Increased cost of testing	Years 0-4 EU-based: €16.6million/y Non-EU based: €11.5 million/y	Year 5 onwards EU-based: €15.9 million/y Non-EU based: €11.1 million/y	Not assessed in this report. No real impact envisaged	Not assessed in this report. No real impact envisaged	

Testing laboratories	Increased use of their sample testing services	Revenues will counterbalance losses for EEE manufacturers	No impact	No impact	
WEEE shredders	No impact	No impact	Exposure of workers raises no concern (RCR<1)	Avoidance of MCCPs releases: 0.75 t/y to air	
PVC recyclers (shredders) and converters	No impact	No impact	Marginal risks to worker health avoided (RCRs between 1 and 2). The EU RAR did not identify an unacceptable risk to workers' health under all PVC-related scenarios examined	Avoidance of MCCPs releases: 2.35 t/y to air and 1.02 t/y to water	
EEE users (consumers)	Increased cost of EEE, if costs are passed on to end user	Insignificant <€1 per large appliance	No changes. EU RAR did not identify any concern for consumer exposure from PVC applications	Not changes. EU RAR did not identify any concern for human exposure via the environment from PVC applications	

No impacts on employment are envisaged.

An analysis of impacts on SMEs cannot be provided due to the lack of specific information, although it is known that in the field of plastic conversion, the presence of SMEs is significant⁶³. SMEs may have limited resilience when faced with increased raw material and regulatory compliance costs.

9.11 Input from consultation with industry stakeholders

The extent of contributions made by industry stakeholders to the analysis presented above has unfortunately been below expectations. In the last consultation the Swedish Chemicals Agency received five responses from trade associations and companies. Their main comment was that there is a lack of suitable alternatives to MCCP.

For clarification, the template used for this analysis is the same used earlier for the phthalates, already restricted under RoHS and HBCDD, not restricted under RoHS.

It can be assumed that MCCPs is an important additive to the manufacture of PVC cables. However the criticality of its use is grounded on its cost and its combination of functionalities. Therefore, alternatives would probably be possible to find, albeit at a cost. This should not be assumed, however, to mean that there will not be particular PVC applications for which reformulation might be more demanding or the re-qualification of products might be more time-consuming.

By way of example, replacing MCCPs in PVC cabling used in medical devices might require a longer substitution period; a study undertaken on behalf of associations relevant to the medical devices industry in 2014 indicated that the medical devices industry would need additional time to implement a RoHS restriction on four phthalate plasticisers. The study notes, “*When a substitution is required, this may involve redesign, testing for reliability and for patient safety and to obtain the data needed to gain approval in the EU and in the rest of the world. This can take many years especially if the change in design is significant which may occur when a new substance restriction is proposed*” (ERA, 2014). In cases where the industry needs more time to introduce an alternative to a substance restricted under the RoHS Directive, there is a procedure for temporary exemptions prescribed in Article 5 of the Directive.

⁶³ A recent document by the European Plastic Converters (EuPC) notes, “*EuPC (...) represents close to 50,000 companies, producing over 45 million tonnes of plastic products every year. (...) More than 1.6 million people are working in about 50,000 companies (mainly small and medium sized companies in the converting sector)*”. Available at <https://echa.europa.eu/documents/10162/48252319-d727-42aa-8b3e-bb97cb218f0e> (accessed on 26 August 2016).

10 Rationale for inclusion of the substance in Annex II of RoHS

10.1 Hazard and risk

10.1.1 Hazardous classification and intrinsic properties

MCCPs are classified as hazardous according to the CLP Regulation. This group of substances is highly toxic to aquatic organisms (Aquatic acute 1 (H400) and Aquatic chronic 1 (H410)), so their uses may be associated with environmental risks. They are also classified as harmful via lactation (H362), although REACH registrants do not propose a hazard classification for this endpoint. Regarding endocrine disrupting properties, MCCPs have been placed under Category 1 for human health, meaning that there is at least one *in vivo* study in animals showing endocrine disrupting activity.

Apart from meeting the T criterion of PBT substances, MCCPs meet the screening criterion for P/vP, taking into account available degradation data for SCCPs. Furthermore, based on the available information on bioaccumulation examined in the EU RAR and during the more recent Substance Evaluation, the balance of evidence is that C₁₄ congeners with 40-50% wt. chlorination meet the criteria for very bioaccumulative substances (BCF > 5000), while C₁₄ congeners with 50-55% wt. chlorination meet the criteria for bioaccumulative substances (BCF > 2000); C₁₄ with 55-65% wt. chlorination are a borderline case. There are some question marks regarding the persistence related to different chlorination grade and chain length. Therefore, Echa has requested further tests to be conducted by the registrants in this aspect.

MCCP use is not explicitly restricted at Community level. Some measures relating to MCCPs at national level, e.g. in Germany and Norway, are in place. The focus of the regulators has, so far, been on SCCPs, which have PBT properties, are suspected carcinogens and have been under scrutiny in the context of long range transboundary air pollution. However, the presence of SCCPs in technical MCCPs products from China has been referred to in the past and has recently been demonstrated in research undertaken in China (Yin, 2016).

10.1.2 Releases and exposure during WEEE treatment

Six waste management processes have been found to be of relevance to exposure estimation, with only the first four directly affecting human health:

- Shredding of WEEE that is collected separately;
- Shredding of PVC cable waste;
- Formulation of PVC recyclate;
- Conversion of PVC recyclate into new PVC articles;
- Landfilling of WEEE and PVC cable waste; and
- Incineration of WEEE and PVC cable waste.

It is assumed that 15,000 t/y MCCPs enter the EU market within EEE and modelling have been used to estimate releases of and exposure to MCCPs. The results might be underestimated though since the 59 % of the WEEE exported to third countries remains unaccounted or is present in MSW alongside other household waste. The volume of WEEE entering the waste handling process, e.g. collection, recycling and disposal, is lower than the theoretical available volume if also taken into account these volumes.

In relation to human exposure, the focus has been on worker exposure during shredding of WEEE and PVC cable waste and the formulation and conversion of recycled PVC. The long-term inhalative exposure estimates vary between 6×10^{-4} to 2.8 mg/m^3 while the long-term dermal exposure estimates vary between 8×10^{-4} to 5.6 mg/m^3 . The number of exposed workers in WEEE treatment installations, PVC recyclers and PVC compounders is estimated at 3,750-8,750, as shown in **Table 36**.

An analysis of chlorinated paraffins in pooled Swedish breast milk from 1996-2010 show a mean level for MCCPs of 14 ng/g fat weight and a maximum level of 30 ng/g fat weight (Danish EPA, 2014).

Through a series of assumptions on the fate of this EEE at the end of its service life, it can be estimated that 7.73-9.37 t/y MCCPs are released to air with a further 22.2 t/y MCCPs released to water. The vast majority of releases are associated with the landfilling of MCCP-containing waste.

These estimates do not take into account releases from WEEE that is unaccounted for and is – presumably – exported but may well be disposed of with little consideration for releases of toxic chemicals to the environment. In addition, WEEE material streams are mechanically treated several times during the whole treatment process, thus the actual releases might even be higher than what has been estimated in this report.

By way of comparison, a UK Annex XV restriction report estimates that the total EU emissions of MCCPs to air in 2006 were approximately 132 tonnes and to water approximately 398 tonnes (not including waste remaining in the environment) (UK CA, 2008).

10.1.3 Human health and environmental risk estimates

Unacceptable risks to workers' health can be identified for a small number of the scenarios considered and when the most stringent DNEL for carcinogenicity of 1.6 mg/m^3 is used (presented in the EU RAR) see **Table 32**. Only for shredding of PVC cable waste (PROC24c) and conversion of PVC recyclate (PROC6), inhalation and dermal exposure respectively lead to RCR values between 1 and 2 in both cases. If the lactation or registration DNELs are used (the former, as given in the EU RAR), however, no risk for the workers is identified. Concern is identified for man via the environment in the two scenarios formulating (RCR = 1.36) and conversion (RCR = 2.21) of PVC. This concern may however be the result of an overestimated daily human exposure via environmental routes.

With regard to environmental risks, some RCRs for PVC formulation and conversion, as well as two RCR values for the landfilling of WEEE and PVC waste and one RCR value for the incineration, are above 1, indicating a risk. The RCR values for the scenarios for soil, secondary poisoning for freshwater and marine fish and marine fish top predators are all below 1. RCR values above 1 have been identified for:

- Formulation of PVC: sediment (1.44), marine water (2.92) and secondary poisoning via the earthworm food chain (2.43);
- Conversion of PVC: freshwater (1.02), sediment (2.62), marine water (5.45) and secondary poisoning via the earthworm food chain (4.10); and
- Landfilling of WEEE and PVC waste: sediment (2.048), secondary poisoning via the earthworm food chain (1.026)
- Incineration of WEEE and PVC waste: secondary poisoning via the earthworm food chain (1.026)

Monitoring data near WEEE sites in EU are lacking. Studies from third countries show environmental contamination with MCCP. In China, a mean level of 21,000 ng/g MCCPs in pond sediments was measured in an e-waste recycling site. In other sediments in China, the MCCPs concentrations ranged from not detected to 16.6 ng/g dry weight. In biota, snakes in China showed the highest concentrations of chlorinated paraffins; 200–340 µg/g lipid weight. For secondary poisoning in the EU RAR, almost all uses of MCCPs lead to a possible risk of secondary poisoning via the earthworm food chain and many of these also indicated a risk via the fish food chain. In this restriction proposal, concern for secondary poisoning is identified via the earthworm food chain for formulation, conversion of PVC and landfill and incineration of WEEE and PVC waste.

For landfilling and incineration of MCCP-containing WEEE and PVC waste, for which RCRs for sediment and earthworm food chain higher than 1 have been estimated, it can be assumed that appropriate RMMs should minimize releases of MCCPs to the environment. However, if appropriate RMMs are not used there might be substantial releases of MCCP and thus a concern for the environment.

10.1.4 Key parameters of the risk assessment

There are a few key parameters influencing the results of the risk assessment. Both the annual quantity of MCCPs present in WEEE, and the fate of this WEEE, are subject to uncertainty and this has been estimated on the basis of several assumptions;

- The volume of WEEE entering the waste handling process e.g. collection, recycling and disposal is lower than the theoretical available volume if also taken into account the volumes ending up as export to third countries, recycled under non-compliant conditions in Europe or scavenged for valuable parts. This affects both the human and the environmental exposure estimation, and in this report the estimations may be too low.
- Information on the actual exposure control measures is not available. Whilst some assumptions may be unduly conservative (e.g. releases from well-operated landfills or incinerators), other assumptions (e.g. the presence of LEV during PVC formulation and conversion) may be too optimistic; and
- Exposure estimates are derived with the use of models and the input of specific information. EUSES in particular does not include specific scenarios for waste management. Thus manual entry of release factors has been opted for. Actual monitoring data and/or a more detailed understanding of the processes involved would be required before the above results could be further refined.
- In addition, it is important to recognize that this restriction proposal focus on the use of MCCP in electrical and electronic equipment and that all other uses of MCCP outside of that scope therefore are excluded in the exposure assessment. As 40-45% of MCCP used within the EU have other uses than PVC, this will to varying degrees result in underestimations of the derived RCRs.

10.2 Impact on waste management

MCCPs are not known to interfere with the collection and processing of WEEE and their potential replacement would similarly not foreseeably cause any waste management problems.

10.3 Available alternatives

A variety of alternatives for MCCPs can be identified in the open literature, including longer chain chloro alkanes (LCCPs), phthalates, adipates, citrates, trimellitates, phosphates and aluminium hydroxide. Alternative cable insulation materials are also known to exist. The consumption of MCCPs has been declining in recent years and this suggests that users are

gradually converting to other technically feasible alternatives. It is acknowledged, however, that MCCPs have (a) a relatively low cost and (b) a combination of plasticising and flame retardancy properties. This means that (i) their replacement may increase raw material costs, and (ii) a single alternative cannot replace MCCPs across all applications because many of the potential alternatives cannot combine the required plasticising and flame retardant functionalities. However, MCCPs are not irreplaceable, and safer, technically feasible alternatives (including alternative materials) can be found.

10.4 Socio-economic impacts

A restriction on the use of MCCPs in EEE might not encompass the entire tonnage of MCCPs placed on the EU market (as it would not apply to cables rated >250 Volts). It would result in a significant reduction though, if not elimination, of the placing of MCCP-containing EEE on the EU market. This would thus greatly reduce the amount of MCCPs released during EEE waste management, as well as the accompanying environmental and (potential) human health risks. Similar benefits could also arise outside the EU. A restriction would also improve the environmental credentials of those EEE manufacturers who place their products on the EU market.

These benefits would be partly counter-balanced by certain costs, both for raw materials (due to the replacement of MCCPs by more costly alternatives) but also for compliance with the requirements of the RoHS Directive. On the basis of limited information, the quantifiable portion of the costs has been found to be up to €4.8 million in investment costs and €7 million/y in ongoing raw material cost increase. An estimate on the cost of requalification and re-certification of MCCPs cable insulation materials cannot be provided. It is generally expected that this cost will be passed on downstream and some of it will be borne by non-EU EEE and EU manufacturers. Ultimately, this cost is a small fraction of the gross operating surplus of the EU electrical equipment manufacturing industry and would translate into an increase of less than €1 in the market price of a large household appliance placed on the EU market. No discernible impact on jobs or the competitive position of the EU industry are envisaged.

On the other hand, there might be an administrative burden for enforcing a restriction on the use of MCCPs since there are difficulties associated with the detection and quantification of MCCPs.

10.5 Conclusions

It is recommended to include MCCP in Annex II to the RoHS-Directive because:

- The environmental classification shows that MCCPs is highly toxic to aquatic organisms. Furthermore, some MCCP congeners (depending on the chlorination grade and chain length) appear to meet the criteria for PBT substances;
- MCCPs is also classified as “May cause harm to breast-fed children” which indicates that the group of substances may affect the human health;
- A risk for workers arising from shredding of PVC cable waste and conversion of PVC recycle is expected;
- There is a risk for the environment caused by WEEE treatment processes such as formulation and conversion of PVC. There might also be a concern for the environment for landfilling and incineration of WEEE of PVC waste;
- For secondary poisoning, formulation and conversion of PVC lead to a possible risk for poisoning of predators via the earthworm food chain. Furthermore, landfilling and

incineration of WEEE of PVC waste might lead to a possible poisoning via the earthworm food chain if not operated under the strict conditions prescribed by regulation;

- A risk for the environment in third countries is expected;
- Alternatives with a more benign hazard profile are available, but may come at a higher cost and an increased administrative burden for industry and Member State authorities.
- Costs from a restriction on EU industry and, ultimately, EU consumers would overall be modest when compared to the value of the EEE market in the EU; and
- Imported commercial electric and electronic equipment containing MCCP may also contain SCCPs.

As the use of SCCPs is phased out (restriction on SCCP in the Stockholm Convention) the production and use of MCCPs and other mixtures of chlorinated paraffines could increase.

The proposed maximum concentration value of MCCPs to be tolerated in EEE is 0.1% by weight per homogenous material. Given the level of risk identified when assuming a typical MCCP concentration in PVC of up to 10-15%, it can be expected that a maximum concentration of 0.1% by weight could significantly reduce the risks demonstrated by exposure modelling.

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Annex I

Worker exposure scenario assumptions used in ECETOC TRA modelling

Table 43. Worker exposure scenario assumptions used in ECETOC TRA modelling

Scenario name	Shredding of WEEE collected separately			Shredding of PVC cable waste			Formulation of PVC recyclate								Conversion of PVC recyclate							
	24a	24b	24c	24a	24b	24c	1	2	3	4	8a	8b	14	15	2	3	4	6	8a	8b	14	21
Process Category (PROC)																						
Type of setting	Professional			Professional			Industrial								Industrial							
Is substance a solid? (yes/no)	Yes			Yes			Yes								Yes							
Dustiness of solids (high/medium/low)	Medium			Medium			Low								Low							
Duration of activity [hours/day]	>4 hours (default)			>4 hours (default)			>4 hours (default)								>4 hours (default)							
Use of ventilation?	Outdoors			Outdoors			Indoors with LEV								Indoors with LEV							
Use of respiratory protection and, if so, minimum efficiency?	No			No			No								No							
Substance in preparation?	<1%			1-5%			1-5%								5-25%							
Dermal PPE / Gloves	No			No			No								No							
Consider LEV for dermal exposure?	No			No			No								No							

Estimated worker exposure to MCCPs during WEEE treatment

Table 44. Estimated worker exposure to MCCPs during WEEE treatment – Estimates generated by ECETOC TRA

Scenario name (PROC #)	Long-term Inhalative Exposure Estimate (mg/m ³)	Long-term Dermal Exposure Estimate (mg/kg/day)	Short-term Inhalative Exposure Estimate (mg/m ³)	Local Dermal Exposure Estimate (µg/cm ²)	Notes/comments on exposure estimates
Shredding of WEEE collected separately (24a)	2.10E-01	2.83E-01	8.40E-01	1.00E+01	
Shredding of WEEE collected separately (24b)	3.50E-01	2.83E-01	1.40E+00	1.00E+01	
Shredding of WEEE collected separately (24c)	1.40E+00	2.83E-01	5.60E+00	1.00E+01	
Shredding of PVC cable waste (24a)	4.20E-01	5.66E-01	1.68E+00	2.00E+01	
Shredding of PVC cable waste (24b)	7.00E-01	5.66E-01	2.80E+00	2.00E+01	
Shredding of PVC cable waste (24c)	2.80E+00	5.66E-01	1.12E+01	2.00E+01	
Formulation of PVC recyclate (1)	2.00E-03	6.86E-03	8.00E-03	2.00E+00	LEV efficiency inhalation [%]: 0, LEV efficiency dermal [%]: 0, LEV is not a exposure modifier for PROC 1
Formulation of PVC recyclate (2)	2.00E-04	2.74E-01	8.00E-04	4.00E+01	LEV efficiency inhalation [%]: 90, LEV efficiency dermal [%]: 0
Formulation of PVC recyclate (3)	2.00E-03	1.37E-01	8.00E-03	4.00E+01	LEV efficiency inhalation [%]: 90, LEV efficiency dermal [%]: 0
Formulation of PVC recyclate (4)	5.00E-01	1.37E+00	2.00E+00	2.00E+02	LEV efficiency inhalation [%]: 90, LEV efficiency dermal [%]: 0
Formulation of PVC recyclate (8a)	1.00E+00	2.74E+00	4.00E+00	2.00E+02	LEV efficiency inhalation [%]: 90, LEV efficiency dermal [%]: 0

Formulation of PVC recyclate (8b)	2.50E-01	2.74E+00	1.00E+00	2.00E+02	LEV efficiency inhalation [%]: 95, LEV efficiency dermal [%]: 0
Formulation of PVC recyclate (14)	2.00E-01	6.86E-01	8.00E-01	1.00E+02	LEV efficiency inhalation [%]: 90, LEV efficiency dermal [%]: 0
Formulation of PVC recyclate (15)	1.00E-01	6.86E-02	4.00E-01	2.00E+01	LEV efficiency inhalation [%]: 90, LEV efficiency dermal [%]: 0
Conversion of PVC recyclate (2)	6.00E-04	8.23E-01	2.40E-03	1.20E+02	LEV efficiency inhalation [%]: 90, LEV efficiency dermal [%]: 0
Conversion of PVC recyclate (3)	6.00E-03	4.11E-01	2.40E-02	1.20E+02	LEV efficiency inhalation [%]: 90, LEV efficiency dermal [%]: 0
Conversion of PVC recyclate (4)	3.00E-02	4.11E+00	1.20E-01	6.00E+02	LEV efficiency inhalation [%]: 90, LEV efficiency dermal [%]: 0
Conversion of PVC recyclate (6)	6.00E-03	1.65E+01	2.40E-02	1.20E+03	LEV efficiency inhalation [%]: 90, LEV efficiency dermal [%]: 0
Conversion of PVC recyclate (8a)	3.00E-02	8.23E+00	1.20E-01	6.00E+02	LEV efficiency inhalation [%]: 90, LEV efficiency dermal [%]: 0
Conversion of PVC recyclate (8b)	3.00E-03	8.23E+00	1.20E-02	6.00E+02	LEV efficiency inhalation [%]: 95, LEV efficiency dermal [%]: 0
Conversion of PVC recyclate (14)	6.00E-03	2.06E+00	2.40E-02	3.00E+02	LEV efficiency inhalation [%]: 90, LEV efficiency dermal [%]: 0
Conversion of PVC recyclate (21)	6.00E-02	1.70E+00	2.40E-01	6.00E+01	LEV efficiency inhalation [%]: 90, LEV efficiency dermal [%]:

Risk Characterisation Ratios for worker exposure to MCCPs during WEEE treatment

Table 45. Risk Characterisation Ratios for worker exposure to MCCPs during WEEE treatment – Estimates generated by ECETOC TRA (DNEL = 1.6 mg/m³)

Scenario name (PROC #)	Risk Characterisation Ratio - Long-term - Inhalation	Risk Characterisation Ratio - Long-term - Dermal	Risk Characterisation Ratio - Long-term - Total Exposure
Shredding of WEEE collected separately (24a)	1.31E-01	2.46E-02	1.56E-01
Shredding of WEEE collected separately (25b)	2.19E-01	2.46E-02	2.43E-01
Shredding of WEEE collected separately (24c)	8.75E-01	2.46E-02	9.00E-01
Shredding of PVC cable waste (24a)	2.63E-01	4.92E-02	3.12E-01
Shredding of PVC cable waste (24b)	4.38E-01	4.92E-02	4.87E-01
Shredding of PVC cable waste (24c)	1.75E+00	4.92E-02	1.80E+00
Formulation of PVC recyclate (1)	1.25E-03	5.96E-04	1.85E-03
Formulation of PVC recyclate (2)	1.25E-04	2.39E-02	2.40E-02
Formulation of PVC recyclate (3)	1.25E-03	1.19E-02	1.32E-02
Formulation of PVC recyclate (4)	3.13E-01	1.19E-01	4.32E-01
Formulation of PVC recyclate (8a)	6.25E-01	2.39E-01	8.64E-01
Formulation of PVC recyclate (8b)	1.56E-01	2.39E-01	3.95E-01
Formulation of PVC recyclate (14)	1.25E-01	5.96E-02	1.85E-01
Formulation of PVC recyclate (15)	6.25E-02	5.96E-03	6.85E-02
Conversion of PVC recyclate (2)	3.75E-04	7.16E-02	7.19E-02
Conversion of PVC recyclate (3)	3.75E-03	3.58E-02	3.95E-02
Conversion of PVC recyclate (4)	1.88E-02	3.58E-01	3.77E-01
Conversion of PVC recyclate (6)	3.75E-03	1.43E+00	1.43E+00
Conversion of PVC recyclate (8a)	1.88E-02	7.16E-01	7.34E-01
Conversion of PVC recyclate (8b)	1.88E-03	7.16E-01	7.17E-01
Conversion of PVC recyclate (14)	3.75E-03	1.79E-01	1.83E-01
Conversion of PVC recyclate (21)	3.75E-02	1.48E-01	1.85E-01

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