Swedish Chemicals Agency

Study of a possible restriction of MCCP in electrical and electronic equipment regulated under RoHS

PM 2/17

KEMI

Swedish Chemicals Agency

The Swedish Chemicals Agency is supervisory authority under the Government. We work in Sweden, the EU and internationally to develop legislation and other incentives to promote good health and improved environment. We monitor compliance of applicable rules on chemical products, pesticides and substances in articles and carry out inspections. We review and authorise pesticides before they can be used. Our environmental quality objective is A Non-toxic Environment.

Article number: 511 248

Preface

The Swedish Government has in its bill, "Proposition 2013/14: 39 – På väg mot en giftfri vardag – plattform för kemikaliepolitiken" proposed that Sweden should continuously evaluate and identify additional substances that should be regulated by the RoHS Directive. The aim is to contribute to the protection of human health and the environment. Consideration should be given to the particular use patterns and sensitivity of children. The focus should among other things be on electronics for consumer use that generate large amounts of waste and on improving the possibility for profitable and sustainable recycling.

This report is an account of a study with the aim to assess the potential for substitution of medium chained chlorinated paraffins (MCCPs). The aim is also to provide data on a possible candidate for restriction under RoHS. It follows a RoHS Dossier Template for substance assessment. However, it does not conclude whether MCCPs should be restricted under RoHS or not.

Article 6(1) in RoHS sets the rules for amending the list of restricted substances. The European Commission (COM) had to consider in a review an amendment of Annex II before 22 July 2014, and periodically thereafter. In preparation of the 2014 review, the Austrian Umweltbundesamt GmbH conducted a first study on the identification, prioritisation and assessment of potentially relevant chemical substances in electric and electronic equipment (EEE) – which was presented as a priority list. By means of a second study, finalised in May 2014, the priority list was adjusted by also considering quantitative information. From the priority list the Swedish Chemicals Agency has chosen a group of prioritised substances - the MCCPs.

The European Commission may on its own initiative, or following a proposal from a Member State, submit proposals to restrict further substances in Annex II. No Member State has yet submitted a proposal for a restriction of a substance under RoHS.

This report is the result of an investigation performed on a consultancy basis by Risk & Policy Analysts Ltd (RPA) and was written by Byron Georgalas and Panos Zarogiannis. The assignment of the consultant did not comprise to conclude on a rational of inclusion of MCCPs in Annex II of RoHS. Responsible for the project at the Swedish Chemicals Agency was Lisa Anfält, Head of Unit for EU Coordination, and contact person was Johanna Löfbom at the same unit. The opinions and recommendations presented in the report are entirely those of the authors at RPA and do not necessarily reflect the Swedish Chemicals Agency's point of view.

Stockholm, May 2017

Contents

Summary

Medium-chained chlorinated paraffins (MCCPs) are a group of organic substances with a carbon chain length between 14 (C_{14}) and 17 (C_{17}), containing varying amounts of chlorine. The main use of MCCPs is as a secondary plasticiser and flame retardant in flexible PVC used as sheating and insulation jackets for cables and wires. These are commonly used in many household appliances and other electric and electronic equipment (EEE). Typical content of MCCPs in PVC wires and cables is 10-15%. In some recent published studies the yearly consumption in the EU is estimated to 15,000 tonnes of MCCPs in EEE.

MCCPs are classified in the EU as 'May cause harm to breastfed children' (Lactation), 'Very toxic to aquatic life' (Aquatic acute 1) and 'Very toxic to aquatic life with long lasting effects' (Aquatic chronic 1).

MCCPs have been registered under the Reach Regulation and most likely meet the PBT-criteria of REACH Annex XIII. They meet the screening criterion for persistence (P/vP). The criterion for toxcicity (T) is met. Furthermore, based on the available information C_{14} congeners with 40-50% wt. chlorination meet the criterion for very bioaccumulative (vB) substances (BCF above 5000), while C_{14} congeners with 50-55% wt. chlorination meet the criterion for bioaccumulative (B) substances (BCF above 2000); C_{14} with 55-65% wt. chlorination is a borderline case. Short-chained chlorinated paraffins (SCCPs) have PBT properties and are also suspected carcinogens. There are some commercial MCCP products that contain SCCPs.

The key treatment processes for MCCP-containing waste (e.g. PVC) that is extracted from separately collected waste of electric and electronic equipment (WEEE) are landfilling, incineration, conventional mechanical recycling, non-conventional mechanical recycling and uncontrolled disposal in third countries (export). Based on literature and assumptions, the total release of MCCPs from WEEE management operations within the EU is approximately 8-9 tonnes per year to air and 22 tonnes per year to water.

Exposure of workers to MCCPs in WEEE processing and PVC waste recycling plants can occur during the processes of shredding and recycling. If no respiratory protection equipment or gloves are used, risks for workers involved in shredding of PVC cable waste and conversion of PVC recyclate are identified. With regard to environmental risks, PVC formulation and conversion, as well as landfilling of WEEE can be of concern.

With regard to potential alternatives, long-chained chlorinated paraffins (LCCPs) and other plasticisers are commercially available. However, it is unlikely that one single substance can substitute the MCCPs across all its uses since MCCPs function as both plasticiser and flame retardant. Phthalates (e.g. DINP and DIDP) 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. However, MCCPs can be substituted, and technically feasible alternatives can be found.

The report does not conclude whether MCCPs should be restricted under RoHS or not. However, it shows that a restriction on the use of MCCPs in EEE would result in a significant reduction of tonnage of MCCP used, and would thus greatly reduce the amount of MCCPs released during EEE waste management, as well as reducing 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 from a restriction would be partly counterbalanced 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. Costs from a restriction on EU industry and, ultimately, EU consumers, would though overall be modest when compared to the value of the EEE market in the EU.

Sammanfattning

Medellånga klorparaffiner (MCCP) är en grupp organiska ämnen med en kolkedjelängd mellan 14 (C14) och 17 (C17) kolatomer innehållande varierande mängder klor. MCCP används främst som sekundär mjukgörare och flamskyddsmedel i mjuk PVC, som används som mantling och isolering av kablar och sladdar. Dessa används ofta i många hushållsapparater och annan elektrisk och elektronisk utrustning (EEE). PVC-sladdar och kablar brukar innehålla 10-15% MCCP. I några nyligen publicerade studier uppskattas den årliga förbrukningen i EU till 15 000 ton MCCP i EEE.

MCCP är klassificerad i EU som "Kan skada spädbarn som ammas" (Lact), "Mycket giftigt för vattenlevande organismer" (Aquatic acute 1) och "Mycket giftigt för vattenlevande organismer med långtidseffekter" (Aquatic acute 1).

MCCP har registrerats enligt Reach-förordningen och uppfyller sannolikt PBT-kriterierna i bilaga XIII i Reach. De uppfyller kriteriet för persistens (P / vP). Kriteriet för toxicitet (T) är uppfyllt. Baserat på tillgänglig information uppfyller C14-varianter med 40-50 viktprocent klor kriteriet för mycket bioackumulerande (vB) ämne (BCF över 5000) medan C14-varianter med 50-55 viktprocent klor uppfyller kriteriet för bioackumulerande (B) ämne (BCF över 2000). C14 med 55-65 viktprocent klor är ett gränsfall. Korta klorparaffiner (SCCP) har PBT-egenskaper och är också misstänkt cancerframkallande. Det finns kommersiella MCCP-produkter som innehåller SCCP.

Nyckelprocesserna för MCCP-innehållande avfall (t.ex. PVC) som sorterats ut från separat insamlat avfall av elektrisk och elektronisk utrustning (WEEE) är deponering, förbränning, konventionell mekanisk återvinning, icke konventionell mekanisk återvinning och okontrollerat bortskaffande i tredje land (export). Baserat på litteraturen och antaganden är det totala utsläppet av MCCP från WEEE-verksamheter i EU cirka 8-9 ton per år till luft och 22 ton per år till vatten.

Exponering av arbetare för MCCP i avfallsbehandlingen av EEE och i PVC-återvinningsanläggningar kan ske under fragmenterings- och återvinningsprocesser. Om inget andningsskydd eller handskar används finns risker identifierade för arbetare vid fragmentering av PVC-kabelavfall och omvandling vid PVC-återvinning. När det gäller miljörisker utgör PVC-formulering och -omvandling samt deponering av WEEE en risk.

Med avseende på potentiella alternativ är långa klorparaffiner (LCCP) och andra mjukgörare kommersiellt tillgängliga. Det är emellertid osannolikt att ett enda ämne kan ersätta MCCP i alla dess användningar eftersom MCCP både är mjukgörare och flamskyddsmedel. Ftalater (t.ex. DINP och DIDP) är mjukgörare till PVC som uppvisar tekniska fördelar jämfört med MCCP och har länge använts som sådana, men de saknar de kombinerade mjukgörande och flamskyddande effekterna som MCCP har och de är dyrare. Men MCCP kan ersättas och tekniskt genomförbara alternativ finns.

Rapporten innehåller ingen slutsats om huruvida MCCP bör begränsas i RoHS eller inte. Den visar däremot att en begränsning av användningen av MCCP i EEE skulle leda till en

betydande minskning av mängden använd MCCP och skulle därigenom avsevärt minska mängden MCCP som släpps ut under hantering av EEE-avfall samt minska risken för miljön och den potentiella risken för människors hälsa. Liknande fördelar kan också uppstå utanför EU. En begränsning skulle också förbättra miljökvaliteten hos de europeiska tillverkarna av EEE som sätter sina produkter på EU-marknaden.

Fördelarna med en begränsning kan vägas mot ökade kostnader, för råvaror (på grund av att MCCP ersätts av dyrare alternativ) men också för att uppfylla kraven i RoHS-direktivet. Industrins kostnader för en begränsning och i sista hand för konsumenterna i EU skulle i allmänhet vara små jämfört med värdet av EEE-marknaden i EU.

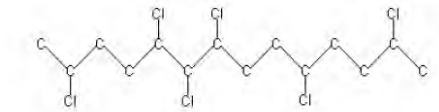
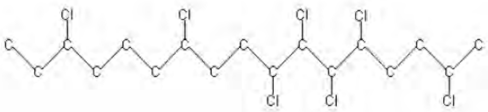
1 Identification, classification and labelling, legal status and use restrictions

1.1 Identification

1.1.1 Name, other identifiers and composition of the substance

Alkanes, C_{14-17}, 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).

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	$C_xH_{(2x-y+2)}Cl_y$, 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)	

As substances of unknown or variable composition (UVCB), MCCPs are complex heterogeneous substances, for which no representative substance can be determined. There are two other commercially produced groups of chlorinated paraffins, namely short-chain (SCCPs), with carbon chain lengths between 10 and 13, and long-chain (LCCPs), having 18 or more carbons.

MCCPs are anthropogenic in nature and are normally found on the market in commercial mixtures. Commercial grade MCCPs contain several components and are liquids at room temperature, with very low volatility and solubility in water[1]. 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, and standard analytical methods do not permit separation and identification of these. Presence of impurities mainly depends on the purity of the paraffin feedstock used for their production; these feedstocks contain no more than 1-2% iso-paraffins and <100 mg aromatics per kg. Most common impurities are iso-paraffin isomers and very low quantities of aromatics. Content of short- or long-chain paraffins is low (<1%) as a result of production policies of the MCCP manufacturers. In the registration dossier there is no mention of impurities or additives.

Around 40 CAS numbers have been used to describe the whole chlorinated paraffin family (including SCCPs, MCCPs and LCCPs, among others) at one time or another. Some of these may be in use for the sole purpose of compliance with national or regional chemical inventories, while others may not be in use any more. It is possible that some of these CAS numbers cover the MCCPs group. Those that might are listed in **Table 2.**

Table 2: EC and CAS numbers under which MCCPs can be grouped

Substance	CAS no.	EINECS no.
Alkanes, C_{6-18}, chloro	68920-70-7	272-924-4
Alkanes, C_{10-21}, chloro	84082-38-2	281-985-6
Alkanes, C_{10-26}, chloro	97659-46-6	307-451-5
Alkanes, C_{10-32}, chloro	84776-06-7	283-930-1
Paraffins (petroleum, normal C>10, chloro	97553-43-0	307-202-0
Alkanes, chloro	61788-76-9	263-004-3
Source: (ECB, 2005), adapted by RPA		

1.1.2 Physico-chemical properties

Since the commercial grade MCCPs contain many components, the physico-chemical properties of the various products can vary. Representative values have therefore been selected for the key parameters used for environmental modelling. **Table 3** summarises the physico-chemical properties of MCCPs as found in ECHA's registration data dissemination portal. According to the registrants' comments, the information was mostly extracted from the EU Risk Assessment Report of 2005 (ECB, 2005).

Table 3: Overview of physico-chemical properties of MCCPs

[1] ECHA registration data dissemination portal, available online at: http://echa.europa.eu/information-on-chemicals/registered-substances, accessed on 2 November 2015.

Property	Chlorine content (%wt)	Value	Remarks
Physical state (20°C, 101.3 kPa)	40-63	Liquid	
Flash point	>40	>210 °C	Determined via closed cup test
Melting/freezing point (pour point)	Not specified (up to 63%)	-50 to 25 °C	Commercial MCCP mixtures do not have a specific melting point but they “pour” when heated over a range of temperatures
Boiling point	Not specified	>200 °C	Decomposition with release of HCl
Density	41	1.095 g/cm^3 at 20 °C	Density increases with increasing degree of chlorination
	56	1.315 g/cm^3 at 20 °C	
	40-58	1.1-1.4 g/cm^3 at 25 °C	
	56	1.28-1.31 g/cm^3 at 60 °C	
Vapour pressure	45	2.27 x10^{-3} Pa at 40 °C	A value of 2.7x10^{-4} Pa at 20 °C is used for environmental assessment
		0.16 Pa at 80 °C	
	52	1.3 x10^{-4} –2.7 x10^{-4} Pa at 20 °C	
Partition coefficient n-octanol/water	45	5.52-8.21 Log P_{ow}	Measured by a high performance thin layer chromatography method
	52	5.47-8.01 Log P_{ow}	
Water solubility	51	0.005-0.027 mg/l	
Viscosity (kinematic)	Not specified	90-12,000 mm^2/s at 20 °C	Based on four unpublished industry study reports. No information on test methods
		25-1,200 mm^2/s at 40 °C	
Source: ECHA dissemination database, registration information for MCCPs			

1.2 Classification and labelling status

MCCPs are classified as hazardous according to Regulation 1272/2008 (CLP) and were added to Table 3.1 of Annex VI of CLP with the first Adaptation to Technical Progress (ATP01), and listed as 602-095-00-X, as can be seen in **Table 4.**

The group of substances is highly toxic to aquatic organisms, so its uses pose a high environmental risk. It is also classified as harmful via lactation. Regarding endocrine disrupting properties, MCCPs were put under Category 1 for human health (DHI, 2007), meaning that there is at least one *in vivo* animal study showing endocrine disrupting activity[2].

[2] DG Environment website, available online at: http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm, accessed on 6 October 2016.

On the other hand, REACH registrants of MCCPs have proposed a different classification. This retains the environmental hazards classification (Aquatic Acute 1 and Aquatic Chronic 1), but omits the classification for effects via lactation and repeated skin contact. **Table 4** compares these two classifications.

Table 4: Classification of MCCPs according to Part 3 of Annex VI, Table 3.1 (list of harmonized classification and labelling of hazardous substances) of CLP [1]

Hazard class	Hazard statement code	Hazard description
Lactation	***H362***	***May cause harm to breast-fed children***
Aquatic acute 1	H400	Very toxic to aquatic life
Aquatic chronic 1	H410	Very toxic to aquatic life with long lasting effects
	EUH066	Repeated exposure may cause skin dryness or cracking
Note: In bold and italics the hazard that is included in the harmonised classification but not in the registration dossier		

1.3 Legal status and use restrictions

1.3.1 Evaluation history

MCCPs first came under scrutiny under the Existing Substances Regulation (EEC) 793/93 (ESR). Evaluation of the substance group was carried out by the UK competent authorities (CA), HSE and the Environment Agency. The first part of the report, on the environment, was published in 2005 and concluded that there was no need for further information or testing. However, a need to reduce risks to the environment from the uses of MCCPs was identified (ECB, 2005). An update to the RAR was published in 2007 and revisited some of the findings of the initial report.

This report was followed by a transitional Annex XV restriction report, according to Regulation (EU) 1907/2006 (REACH). It was prepared by the UK CA and followed the format of a REACH Annex XV restriction report, but was not used for an official restriction proposal. Nevertheless, it is mentioned that marketing and use of MCCPs in leather fat liquors should be restricted, although the restriction proposal has not been evaluated further (UK CA, 2008).

Evaluation of MCCPs continued under the Community Rolling Action Plan (CoRAP), again by the UK CA. The group was selected due to its high environmental toxicity, potential PBT (persistent, bioaccumulative and toxic) properties, potential for exposure due to wide dispersive use and its high aggregated tonnage[3]. The report concluded that further information was needed to clarify the status of some MCCP components (ECHA, 2014). The registrants disagreed over the substances, for which this information should be extracted, but their subsequent appeal was rejected and the initial conclusions upheld.

[3] CoRAP substance list, available online at ECHA's website: http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table, accessed on 19 August 2015.

It is important to note that none of these initiatives were specifically targeted to the use of MCCPs in EEE.

1.3.2 REACH Regulation (1907/2006)

MCCPs have been registered under the REACH Regulation. There are twelve registrants, including[4]:

- Altair Chimica Spa, Italy;
- BiPRO GmbH, Germany;
- Caffaro Industrie S.P.A., Italy;
- Fortischem a.s., Slovakia;
- Ineos Chlorvinyls Limited, United Kingdom;
- Ineos Enterprises France Z.I., France;
- Kaustik Europe B.V., Netherlands;
- Leuna-Tenside GmbH, Germany;
- Prakash Chemicals Europe B.V., Netherlands;
- Química del Cinca, S.L., Spain;
- REACHLaw Ltd, Finland; and
- Sustainability Support Services (Europe) AB, Sweden.

Evidently, some of these companies are Only Representatives.

MCCPs are included in the priority list of substances for further evaluation of their role in endocrine disruption, as Category 1, meaning that at least one study providing evidence of endocrine disruption in an intact organism exists[5].

The substance was evaluated under the CoRAP, requesting further testing on MCCPs, as described above. At the moment, MCCPs are not included in the Candidate List for Authorisation.

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, they are not included in the registry of intentions for restrictions[6].

1.3.3 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 5** lists the EU legislation (Directives and Regulations) considered in this study.

[4] As named here: https://echa.europa.eu/documents/10162/bcc34f8d-ce53-48cd-9f17-605ad512853a (accessed on 9 October 2016).

[5] List of Category 1 substances available online at: http://eng.mst.dk/topics/chemicals/endocrine-disruptors/the-eu-list-of-potential-endocrine-disruptors/, accessed on 17 November 2015.

[6] Registry of intentions available at: http://echa.europa.eu/web/guest/registry-of-current-restriction-proposal-intentions, last visited on 19 July 2016.

Table 5: 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[7]	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)

1.3.4 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 Water[8]. 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).

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. It does not signify that the Danish EPA has decided to recommend a prohibition of that substance and other means of restricting use are to be considered, such as “classification and labelling, duties on particularly problematical chemicals, stricter standards, voluntary agreements on phase-out, environmental labels, green guidelines for purchasing, positive/negative lists for selected areas, subsidies for substitution initiatives, emission control and information campaigns” (Danish EPA, 2011). It has also been reported in consultation that MCCPs are not used in Sweden for cable manufacturing.

Short chain chlorinated paraffins (SCCPs, alkanes, C_{10-13}, 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%. This

[7] 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.

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

restriction was taken up in REACH Annex XVII. 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 Pollutants[9] 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 as an impurity in an article produced with MCCPs[10]. 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.

Box: Presence of SCCPs in commercial MCCPs products

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, C_{14} carbon chain length was the dominant group, followed by C_{13} and C_{15}. This demonstrates that the commercial MCCP product C-52 is composed of both SCCPs and MCCPs (Yin, 2016). The findings are shown in the figure below

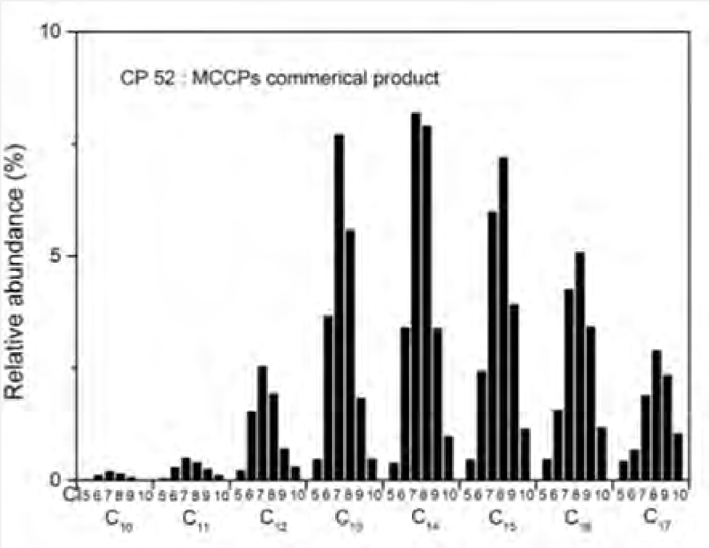


Figure 1: Relative abundance of homologous and congener profile of carbon and chlorine in technical C-52 product in the Chinese market by GC-LRMS (ECNI) (Yin, 2016)

9 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.

10 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, C_{14} carbon chain length was the dominant group, followed by C_{13} and C_{15}. This demonstrates that the commercial MCCP product C-52 is composed of both SCCPs and MCCPs (Yin, 2016).

Nevertheless, on 13 November 2015 Regulation (EC) No 850/2004 was amended by Commission Regulation (EU) 2015/2030 to remove these exemptions and list SCCPs solely in Annex I of the Regulation. This change entered into force on 4 December 2015 and subsequently all uses of SCCPs are prohibited within the EU (and also in Norway) above the previously mentioned limit values.

1.3.5 International agreements

The only international agreement referring explicitly to MCCPs is the Helsinki Convention on the Protection of the Marine Environment of the Baltic Sea Area (Helsinki Convention). MCCPs are considered a substance of specific concern to the Baltic Sea, according to the final report of the HAZARDOUS project (HELCOM, 2009) and a guidance document on measures for emission reduction has been issued under the related COHIBA Project (COHIBA Project Consortium, 2011). MCCPs are also covered by implication by the Basel Convention which includes a waste category for organohalogen compounds in general.

On the other hand, SCCPs are the chlorinated paraffin compounds addressed most often (e.g. included in the UNECE Convention on Long Range Transboundary Air Pollution (LRTAP), the Aarhus Protocol on Persistent Organic Pollutants (LRTAP POPs Protocol), the Stockholm Convention, the List of Substances of Potential Concern of the OSPAR Convention[11] and the Baltic Marine Environment Protection Commission (HELCOM). SCCPs are also regulated under the EU POPs Regulation (EC) No 850/2004 that implements the Stockholm Convention and the LRTAP POPs Protocol within the EU, as described above.

In 2006, the European Union and its Member States submitted a proposal to list SCCPs to the Stockholm Convention. At its second meeting, the Persistent Organic Pollutants Review Committee concluded that SCCPs meet all of the screening criteria specified in Annex D of the Convention. The risk profile for SCCPs was adopted at the eleventh meeting, in October 2015, and the risk management plan in September 2016. Information on the use of MCCPs as an alternative to SCCPs and the fact that commercial MCCPs contain SCCPs is included in the adopted risk management plan for SCCPs. At the meeting of the Parties of the Stockholm Convention in 2017 the recommendation for their listing in Annex A for global elimination will be considered.

In October 2015, the Chemical Review Committee (CRC) of the Rotterdam Convention adopted decision CRC-10/4, and recommended that SCCPs be listed in Annex III to the Convention as industrial chemicals and that a decision guidance document be prepared for the recommended listing. This recommendation will be considered at the meeting of the Parties of the Rotterdam Convention in 2017.

1.3.6 Public initiatives

ChemSec does not include MCCPs in its SIN List, although SCCPs are included due to their PBT properties. The SIN List also includes “Paraffin waxes and Hydrocarbon waxes, chloro” (EC No: 264-150-0, CAS No: 63449-39-8), which have longer carbon chains than MCCPs, based on the fact that several congeners have PBT and/or endocrine disruptor

[11] OSPAR website, LSPC, available online at: http://www.ospar.org/work-areas/hasec/chemicals/possible-concern, accessed on 17 November 2015.

properties[12]. On the other hand, the Trade Union Priority List[13] includes "chlorinated paraffins" which encompasses the CAS/EC numbers for MCCPs with an overall score of 43, bringing this group at No. 2 on the list, it is however noted that the presence of SCCPs is what drives the scoring.

The MCCP User Forum was established in the UK in 2001 by users and suppliers of MCCP. It was responsible for developing a plan to reduce risks from MCCP to the UK environment. It seems, however, that the Forum is not active any more.

1.3.7 Conclusions on legal restrictions

MCCP use is not explicitly restricted at Community level. Specific focus on MCCPs has been given under the Helsinki Convention but, in the main, the focus of the regulators has, so far, been on SCCPs, which have PBT properties and are also suspected carcinogens. Importantly, commercial MCCP products may contain SCCPs (as also confirmed by recent research in China (Yin, 2016)) and SCCPs are in May 2017 to be considered for global phase-out following their listing in the Stockholm Convention. Finally, some measures relating to MCCPs at national level (Germany, Norway) are currently in place.

[12] ChemSec SIN List, available online at: http://sinlist.chemsec.org/, accessed on 10 November 2015.

[13] Trade Union Priority List, available online at: https://www.etuc.org/sites/www.etuc.org/files/Trade_Union_List_version_2-2_21062011_with_2nd_ATP_1.xls, last accessed on 19 July 2016.

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 cables[14].

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 boards[15]. 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 higher degrees of chlorination (typically around 50–52% wt. Cl) (Öko-Institut, 2008).

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

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

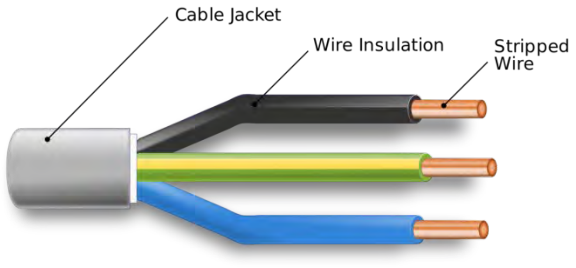

Figure 2: Diagram illustrating location of PVC cable and wire jackets

According to the EU RAR, the content of MCCPs in such applications varies, depending on the intended function. 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 6** summarises the applications of these sealants and adhesives in EEE as presented in the literature.

Table 6: 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[16]
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[17]
Polysulphide	Also used for ‘potting’ purposes in electronic equipment

[16] Information available at: http://polyurethane.americanchemistry.com/Introduction-to-Polyurethanes/Applications, accessed on 28 October 2015.

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

Sealant/adhesive	Details of their use
Acrylic	Acrylic adhesives and sealants are relatively inexpensive and are accompanied by significant thermal and hydrolytic stability limitations. They are normally used in electronics as Pressure Sensitive Adhesives (PSAs)[18]
Butyl rubber	**Butyl rubber is used as condenser packing for electrical appliances. It benefits from low permeability and chemical inertness, is an effective electrical insulator and has good dielectric properties**[19]

It is important to note that sealants and adhesives are not as frequently or as uniformly applied as PVC cable sheaths, and for this reason it is difficult to obtain information on their market share. During consultation, use of MCCPs in polyurethanes intended for EEE was not confirmed, with manufacturers of polyurethane products mentioning that their products are not used in such applications.

2.2.3 Coatings

MCCPs can be used as plasticisers in a number of paints and varnishes used on EEE. Dishwasher racks and tumble dryer ventilation hoses are, for example, often coated with PVC. MCCPs with a chlorine content of 50–60% are used as plasticisers in certain paints, varnishes and other coatings. These substances are generally used at concentrations of 1–5% but they can reach up to 20%. MCCPs may be used as plasticisers in resin-based paints but are most frequently used in chlorinated rubber or copolymer paints. According to a 2011 report, several groups and businesses no longer use MCCPs in their paints or varnishes, and in one case it was specifically stated that a company located in France made a conscious decision to replace their use of MCCPs for LCCPs due to the toxic effect of MCCPs on the environment (INERIS, 2011).

As is the case with adhesives and sealants, it is difficult to estimate how frequently these paints and varnishes are used on EEE. The EU RAR includes information from a 1999 report referring to the content of chlorinated paraffins in coatings. Most of the coatings and lacquers contained chlorinated paraffins in the range of 1-5% w/w, but some products had contents of up to 10% or 20% (ECB, 2005).

2.2.4 Conclusions

The most common use of MCCP, relevant to EEE, is in sheathing and insulation of PVC cables and wires. Other common uses identified in literature are in rubber sheathing and insulation of cables and wires, in adhesives and sealants and in paints and coatings. However, consultation with relevant stakeholders has only confirmed the uses relevant to cables and wires.

[18] Dow Corning, 'Adhesives and Sealants', at: http://www.dowcorning.com/content/etronics/etronicsseal/etronics_newaas_tutorial4.asp, accessed on 28 October 2015.

[19] Exxon Mobil, 'Butyl rubbers for low permeability in consumer products', at: http://www.exxonmobilchemical.com/Chem-English/yourindustry/butyl-rubber-applications-consumer-products.aspx, accessed on 28 October 2015.

Typical content of MCCPs in PVC wires and cables is 10-15%, but in some cases it can be up to 20%. MCCP content in rubbers has been found to be lower, with cases reported of 2.6% and 3.8% content, although there was one reported case of 11% in cables in Norway.

2.3 Types of appliances

2.3.1 Household appliances

Wherever cable or wires are required for electrical or electronic devices there is a high probability that PVC is used. This means that many EEE used in EU households may contain MCCPs. PVC sheathed cables and wires can be found in a wide variety of *electrical* products such as washing machines, refrigerators, hairstyling equipment, internet hubs, telephones and extractor fans, as well as in a wide variety of *electronic* devices such as televisions, radios and computers. In 2012, EU households contained an average of 1.89 television sets[20]. Televisions, along with their associated audio/visual equipment, make use of a large number and variety of cables and wires – all of which are likely to be sheathed in PVC.

In 2014, 93% of the UK adult population owned a mobile phone[21], and according to a poll conducted this year (2015) the average British household owns 7.4 internet devices – many of these devices are likely to require chargers using PVC sheathed cable and wires, and the devices themselves are likely to contain wires, such as accelerometer cables which also use PVC cable sheaths. Further to this, landline telephones are likely to use PVC cables to connect to the telephone socket, and electrical equipment such as hairdryers, fridges, ovens, blenders, coffee machines, bread makers, slow cookers, etc. are all likely to use PVC sheathed cables and wires to connect to the mains power supply, and may also contain PVC sheathed wires internally.

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 meters[22] by 2020 wherever it is cost-effective to do so'[23], consequently a significant number of meters are expected to be disposed of in the coming years, including their cables. **Table 7** lists the types of PVC items that are associated with common household appliances.

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[20] Calculation based on average of figures taken from *TV Sets: Average Number of TV Sets per TV Household (68 countries)*, at: http://www.nakono.com/tekcarta/databank/tv-sets-average-number-of-tv-sets-per-tv-household/, accessed on 28 October 2015.

[21] Ofcom 'Facts & Figures', available online at: http://media.ofcom.org.uk/facts/, accessed on 5 November 2015.

[22] 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.

[23] 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.

Table 7: List of PVC items associated with types of household appliances

Type of Equipment				
TV [a]	**Radios [b,c,d,e]**	**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
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g. http://www.rospa.com/home-safety/uk/northern-ireland/electricity/flexes-cables/flexes/
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i. http://www.screwfix.com/c/heating-plumbing/ducting/cat840506

2.3.2 Medical devices

Use of MCCP in medical devices could not be determined during the preparation of this report, although medical device manufacturers commented during consultation that MCCP presence in medical devices should not be precluded. Information on MCCP quantities was not available and consultees have argued that gathering of the required data may take from 18 months to up to 3 years, due to the complexity of the relevant supply chains.

In the case of medical devices it is important to note that, although MCCPs may not be intentionally added by manufacturers, their presence in components cannot be ruled out, particularly given the very large number of components that can be present in medical devices. It is also important to note that medical devices may be sourced from a wide variety of suppliers – up to 11,000 suppliers over several (5–7) tiers.

2.3.3 Conclusions

MCCP is widely used in PVC sheathed cables and wires. These are commonly used in many household appliances and other EEE. As a result, it can be assumed that all EEE categories using cables are relevant to this analysis. MCCPs are also expected to be present in medical devices, but due to the complexity of the sector's supply chains, it would take a very long period of time, based on previous experience, to map the use of MCCPs there.

2.4 Quantities of the substance used

2.4.1 Production and use of MCCPs

As commented in the EU RAR, an Entec study from 2004 reported figures for the use of MCCPs in 2003, showing that although the majority of MCCPs (around 60%) were used in PVC, consumption was on a declining trend compared to the previous years. Similarly, use of MCCPs in carbonless copy paper had significantly declined to less than 1%. Around 15% of MCCPs were used in metal working/cutting fluids, around 15% used in paints, sealants and adhesives, around 7% in rubber/polymers (other than PVC) and around 4% used in leather fat liquors. Overall, the total volume of MCCPs used in 2003 was around 82% of the 1997 level ((Entec, 2004), reviewed in EU RAR (2005)).

According to 2006 figures included in a 2014 Danish EPA report, 54% of total MCCPs were used as plasticisers/flame retardants in PVC, 18% in paints/coatings, adhesives and sealants, 11% as flame retardants in rubber and other polymers, 16% as lubricants in metal working/cutting fluids and 1% in leather fat liquors (Danish EPA, 2014). **Table 8** compares the estimates of the two studies. A decline in the share in PVC between 2003 and 2006 can be observed, along with a relative increase in use in rubber and other polymers.

Table 8: EU 28: Shares of MCCP use across relevant applications

Application of MCCPs	Entec (2004)	Danish EPA (2014)
Plasticiser/flame retardant in PVC	60%	54%
Paints/coatings and adhesives/sealants	15%	18%
Flame retardants in rubber and other polymers	7%	11%
Lubricants in metal working/cutting fluids	15%	16%
Leather fat liquors	4%	1%
Carbonless copy paper	< 1%	Not mentioned
Reference year	2003	2006

According to the EU RAR, total production capacity of MCCPs in five EU sites was between 45,000 and 160,000 t/y. The total EU consumption of MCCPs has been estimated to have ranged between 56,700 and 65,300 tonnes/year in the past (1994-1997).

A study by the Öko-Institut indicates that approximately 17% of the total 51,827 tonnes of MCCP supplied for PVC applications in 1997 (according to EU RAR data) was used in cable products, and it was therefore assumed that 9,200 tonnes of MCCPs were used per year for cable products (Öko-Institut, 2008). However, further information on EEE applications was not available. Quantities of MCCPs used specifically in sealants and adhesives, and paints and varnishes were not available.

Information submitted through REACH registration by the 2010 deadline shows an annual tonnage range of 10,000-100,000 by 12 registrants, including five manufacturers (INEOS Chlor, Caffaro, Química del Cinca, Leuna Tenside and Novácke Chemické Závody)[24].

The most recent estimation of the quantities of MCCPs used in EEE applications comes from INEOS Vinyl, one of the major manufacturers of MCCPs in the EU, during consultation for a 2014 Öko-Institut report (Öko-Institut, 2014). The company estimated the total EU market for MCCPs at around 40,000 tonnes per year and the amount of MCCPs used in PVC cable formulations at roughly 15,000 t/y. In a 2015 report by KemI, it was estimated that the total amount of MCCPs used in EEE is around 15,000 tonnes (most of which is used as a plasticiser/fire retardant for flexible PVC used in cable sheathing) (KemI, 2015). However, it is likely that this study was reproducing information from the Öko-Institut report. **Table 9** summarises the different estimations on MCCP quantities.

Table 9: EU 28: Manufacture of other electronic and electric wires and cables (NACE 27.32) – Quantities in tonnes

Source	MCCP demand (t/y)	MCCP use in EEE (t/y)	Reference Year (assumed)
EU RAR (ECB, 2005) – Öko-Institut (2008)	45,000-160,000	>9,200	1997
Entec (2008)	63,691	Unknown*	2006
REACH Registration	10,000-100,000	Unknown	2009
INEOS Vinyl's comments on Öko-Institut study (2014)	40,000	15,000	2013
*: Entec's study mentions 34,676 t of MCCP (54%) were used as additives for PVC and 7,077 t as additives for other rubbers and polymers. These numbers cannot however be used to estimate MCCP use in EEE			

No clear trends can be identified from this table, although it seems that, in recent years, demand for MCCPs in the EU may have fallen. The situation regarding uses in EEE is even less clear. Consultees have been unable or unwilling to provide more up to date information. A manufacturing association commented during consultation that they expected demand for MCCPs to decline in the future. Euro Chlor's website suggests that the total EU production

[24] Euro Chlor website, available online at: http://www.eurochlor.org/chlorinated-paraffins-%28cpsg%29/what-are-chlorinated-paraffins.aspx, accessed on 19 August 2015.

of chlorinated alkanes (short-, medium- and long-chained) is approximately 45,000 tonnes per year[25].

It must be noted here that MCCPs use as secondary plasticisers is strongly connected to the use of phthalates, in particular DEHP, which are used as primary plasticisers in PVC. DEHP is in the Authorisation list due to reproductive toxicity and endocrine disrupting properties and its use in PVC has been declining. It is not known how this would affect MCCP demand, however. It is also worth noting that according to information obtained during the preparation of this dossier but cannot be reproduced for copyright reasons, between 2007 and 2016 the volume of polymers used in cable manufacture in Europe has declined and among the different polymers PVC-based compounds have been the worst affected, even if they still account for the largest proportion of the European market. 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.

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.

With respect to wires and cables, the level of detail of the available data includes all electronic and electric wires and cables (PRODCOM Code: 27.32). This code refers to both high and low voltage cables. There is also no distinction between PVC and other cables, so the information in **Table 10** is provided only for illustration. It should be noted that, according to a 2012 report, PVC held almost 60% of the market share for cable sheathing[26].

Table 10: EU 28: Manufacture of other electronic and electric wires and cables (NACE 27.32) – Quantities in tonnes

	2009	2010	2011	2012	2013	2014
Production	4,478,629	4,674,783	4,937,941	4,459,600	3,676,447	4,774,201
Imports	514,787	644,696	666,577	654,784	628,858	677,081
Exports	520,062	567,883	600,038	636,318	662,369	691,075
Source: PRODCOM Database						

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.

[25] Euro Chlor website, available at: http://www.eurochlor.org/chlorinated-alkanes-(casg)/what-are-chlorinated-alkanes.aspx, accessed on 1 August 2016.

[26] Transparency Market Research, 'PVC Materials Segment of Automotive Wire and Cables Market Could Lose Share to XLPE and PPE', available online at http://www.transparencymarketresearch.com/article/automotive-wire-cable-materials.htm, accessed on accessed on 28 October 2015.

Using simple analogy, quantities of MCCPs in imported cables were roughly 2,100 tonnes in 2014[27]. 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.

MCCP in cables can also be imported in the EU as a component of EEE, such as those described in **Table 7** above. **Table 11** shows the imports, exports and production sold of these categories of EEE for 2014.

Table 11: EU 28: Imports, exports and production sold of selected EEE – Quantities in numbers of items

	PCs	Radios	TVs	Refrigerators	Washing machines and tumble dryers
Production	9,630,654	731,564	44,503,486	14,936,648	19,263,660
Imports	104,681,259	24,559,832	53,537,765	13,908,532	No data
Exports	12,107,471	701,120	7,153,779	3,277,235	No data
Source: Eurostat Database (http://ec.europa.eu/eurostat/web/prodcom/data/database)					

It can be seen that imports of EEE are significantly higher than exports. This might indicate that additional quantities of MCCPs are entering the EU market in cables within this equipment. However, it must be noted that some of this imported equipment could be using cables that were originally manufactured in the EU and then exported. This information is not available. Moreover, the presence of MCCPs in the cables used in manufacturing this equipment outside of the EU is uncertain. As a conclusion, import of MCCPs in cables used in EEE manufacture outside of the EU is possible, but the exact quantities are unknown.

2.4.3 Conclusions

The most recent (2014) reports estimate a consumption of 15,000 t/y of MCCP in EEE in the EU. 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 EU[28] and these may contain MCCPs. Stakeholder consultation did not offer any new insights, and the flows of MCCPs in and out of the EU within PVC formulations or finished EEE are uncertain. We therefore assume that imports and exports of MCCPs in PVC and/or EEE are largely

[27] 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÷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 × 0.003 = ca. 2,100 t/y.

[28] As will be shown in Section 5.3.1, 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÷9.1 = 59% of consumption was domestically manufactured EEE and the remaining 41% of EEE consumption was imported from outside the EU.

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. It is possible that this figure is an underestimate.

3 Human health and hazard profile

As UVCB substances, MCCPs are heterogeneous compounds that represent significant challenges to hazard characterisation. The four chain lengths (C_{14-17}) 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 CO_2), 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 C_{15} 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. Inhalation toxicity studies are not available for MCCPs, but data from the structurally similar SCCPs indicate that there is low acute toxicity. MCCPs are of low acute oral toxicity with no deaths and only limited, non-specific clinical signs of toxicity resulting from exposure of rats to very high doses (up to 15,000 mg/kg). The few *in vivo* studies available and information about the structurally similar SCCPs suggest that MCCPs are not acutely toxic by the dermal route (UK HSE, 2008; JRC-IHCP, 2011).

Irritation and sensitisation

No data are available in humans relating to skin or eye irritation. However, based on two standard animal studies, C_{14-17} 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 C_{14-17} 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 C_{14-17} (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 Repeat 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 C_{14-17} 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.

A 90-day repeated dietary exposure study in dogs was reviewed by Birtley et al. (1980). In that study, a group of 4 male and 4 female beagles received 0, 10, 30 or 100 mg/kg/day MCCP (52% chlorination) for 90 days. As the full study report was not available, it is difficult to draw firm conclusions. However, the only findings apparently observed related to the liver. There was reported to be a statistically significant increase in the activity of serum alkaline phosphatase, as well as an increase in relative liver weight, at doses of 100 mg/kg/day, both of which were unquantified in the review.

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" T_4 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 T_4 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 C_{12} 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 ($C_{14\text{-}17}$ 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 α2u-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. Therefore, 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 µg kg-^{1}/day and 0.3 µg kg^{-1}/day, respectively. Dietary exposure contributed 71-100% of the total intake. Increasing concerns, KemI 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 NOAEL for effects on kidneys (inner medullary tubular dilation and 'chronic nephritis') was 0.4 mg/kg body weight/day in a 90-day study. The changes seen at the next exposure level (4 mg/kg body weight or 50 mg/kg food in diet) were slight and increased only marginally in severity at higher levels, indicating a shallow dose-response curve. However, the 23 mg/kg bw/day value calculated for kidney effects in rats after dietary exposure can also be used as the most reliable value. This value translates to 41 mg/m^3 – 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 12** presents the DNELs as calculated in that report. The critical DNELs selected in the report are marked in bold and italics.

The DNEL values used in the MCCPs registration dossier are lower than the values used in the EU RAR. In in the evaluation presented later in this document, the more conservative values of the EU RAR are used. It must be noted that, in the EU RAR no concerns were expressed for consumers or exposure of man via the environment. Furthermore, concerns for workers were raised only for the use of MCCPs in oil-based metal working fluids.

Table 12: DNEL calculation for worker DNEL systemic effects in Annex XV transitional report

Target population (worker)	Starting point	AF*	DNEL	Comments
Inhalation route for kidney effects/carcinogenicity	41 mg/m^3 – 8h TWA (23 mg/kg bw/day)	25	***1.6 mg/m^3***	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
Dermal route	1,150 mg/kg bw/day (50 mg/kg bw.day)	100	***11.5 mg/kg bw/day***	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/m^3) 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 Germany[29]. 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 µg 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 µg kg^{-1} bw/day from a sub-chronic study NOAEL of 0.4 mg kg^{-1} bw/day (Environment Canada, 1993).

[29] GESTIS database of international limit values, available online at: http://limitvalue.ifa.dguv.de/, accessed online on 20 November 2015.

4 Environmental health and 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.

The toxicity of MCCPs has been determined in aquatic and terrestrial biota. MCCPs are classified as being highly toxic to aquatic organisms both acutely and after repeated exposure, having long-term effects. Aquatic toxicity has been observed in tests with invertebrates over chronic exposures. The test substance was a $C_{14\text{-}17}$ 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 EC_{50} 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 $C_{14\text{-}17}$ 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 (*Phasanius colchius*), consequent to a single oral dose of $C_{14\text{-}17}$ 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 (Madely & 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. 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 based their decision based on the simulation degradation studies requested by the UK in the context of Substance Evaluation on a C_{14} chlorinated n-alkane with a chlorine content of 50-52% by weight, a C_{14} chlorinated n-alkane with a chlorine content of 55-60% by weight and a C_{15} 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 (C_{15} 51% wt. chlorination and C_{14} 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 C_{14}, ~45% wt. chlorination and C_{14}, 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 C_{15}, 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).

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). A recent review of the field data by Thompson & Vaughan (2013) suggested that trophic biomagnification is not occurring. Identified by ECHA as of particular relevance, scientific peer-reviewed papers by Fisk *et al*. (1996), (1998) and Cooley *et al*. (2001), were considered in the evaluation (reviewed in the EU RAR (ECB, 2005)). Moreover, in ECHA's decision on Substance Evaluation, it is commented that robust study summaries for these papers shall be submitted.

In conclusion, it seems that characterisation of MCCPs according to the criteria for bioaccumulation is complicated and cannot give a conclusive result. A C_{14}, 45% wt. chlorination congener is considered to bioaccumulate according to a well-documented OECD 305 test referenced in the registration dossier. The BCF values as reported in the registration dossier (available on ECHA's website) were 6660 (whole body, steady state) and 9140 (kinetic). The respective values when normalised for 5% lipid content were 3230 and 4440 (which, if normalised for growth, would exceed 5000). However, information for other congeners is uncertain and varies by carbon chain length and degree of chlorination. The PBT assessment included in the REACH registration dossier considers that MCCPs are not bioaccumulative, although it recognises the results of the test mentioned above.

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.

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 high levels found in terrestrial organisms and birds of prey would suggest that for assessing bioaccumulation one must look at terrestrial ecosystems/food chains rather than aquatic ecosystems/food chains.

4.2.3 Potential for secondary poisoning

As discussed above, MCCPs are persistent and some of the congeners have relatively high bioaccumulation factors. Furthermore, the physicochemical properties of MCCPs, including high Log K_{ow} values (4.47-8.21), render sorption to soil and sediment likely. As a result, there is potential for secondary poisoning. The EU RAR has assessed this potential through the review of a number of relevant studies.

Direct MCCP exposure may occur during manufacturing processes (chlorination), formulation applications (formulation of rubber and paint), use of products and solid waste disposal (BRE, 2008). However, it is widely accepted that the most likely source of release comes from use and disposal in dispersive use applications. The atmospheric half-life of MCCPs has been estimated at 1-2 days and monitoring studies have ubiquitously detected MCCPs in biota, including fish and marine mammals (ECB, 2005). MCCPs were also present in mothers' and cows' milk as is shown in multiple studies, reviewed at the EU RAR (Thomas & Jones, 2002), (Thomas, et al., 2003).

For secondary poisoning, almost all uses of MCCPs lead to a possible risk of secondary poisoning via the earthworm food chain and many of these also indicate a risk via the fish food chain. 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.

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 C_{14} congeners with 40-50% wt. chlorination meet the criteria for very bioaccumulative substances (BCF > 5000) while C_{14} congeners with 50-55% wt. chlorination meet the criteria for bioaccumulative substances (BCF > 2000); C_{14} with 55-65% wt. chlorination are a borderline case. Data available on a C_{15}, 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 13**, adapted from ECHA's decision on Substance Evaluation for MCCPs (ECHA, 2014), shows the estimated P and B properties of MCCP congeners.

Table 13: 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?	P?	P	P

	Not B	Borderline B	Not B	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*.

4.3.2 Evaluation against the Stockholm Convention's POP criteria

The Stockholm Convention has in its Annex D set screening criteria for identifying Persistent Organic Pollutants (POP). These include criteria on persistence, bioaccumulation, long-range transport potential and adverse effects that are to be applied in a flexible and transparent way, taking all information provided into account in an integrative and balanced manner. **Table 14** summarises these criteria and uses them to evaluate MCCPs' POP potential.

Table 14: MCCPs evaluation according to Stockholm Convention's POP criteria

Category	Criterion description	MCCPs properties
Persistence	Half-life in water is greater than two months, or half-life in soil is greater than six months, or half-life in sediment is greater than six months Evidence that the chemical is otherwise sufficiently persistent to justify its consideration within the scope of the convention	No direct data on MCCPs. SCCPs mineralisation half-lives around 1,630-1790 days in freshwater sediment and 335-680 days in marine sediment
Bioaccumulation	Bioconcentration or bioaccumulation factor in aquatic species for the chemical is >5000 or, in the absence of such data, that the log K_{ow} is >5 Chemical presents other reasons for concern, such as high bioaccumulation in other species, high toxicity or ecotoxicity Monitoring data in biota indicating that the bioaccumulation potential of the chemical is sufficient to justify its consideration within the scope of the convention (see also recent findings in the Yangtze River Delta (Zhou, et al., 2016))	BCFs higher than 5000 l/kg have been reported in aquatic species, for the congeners with shorter carbon chains (C_{14}). The typical K_{ow} value for MCCPs is 7, with most congeners having higher than 5. MCCPs have high toxicity for aquatic organisms
Long-range transport	Measured levels of the chemical in locations distant from the sources of its release that are of potential concern Monitoring data showing that long-range environmental transport of the chemical, with the potential for transfer to a receiving environment, may have occurred by way of air, water or migratory species Environmental fate properties and/or model results that demonstrate the above	No relevant information has been collected. It can be further evaluated when biomonitoring data become available

Category	Criterion description	MCCPs properties
Adverse effects	Adverse effects to human health or to the environment that justifies consideration of the chemical within the scope of this convention Toxicity or ecotoxicity data that indicate the potential for damage to human health or to the environment.	MCCPs are classified for acute and chronic aquatic toxicity as well as for potential toxic exposure via lactation. MCCPs have high toxicity for aquatic organisms
Source: Stockholm Convention on persistent organic pollutants (http://chm.pops.int/default.aspx)		

MCCPs would fulfil the Persistence and Adverse effects POP criteria of the Stockholm Convention, provided that the SCCP biodegradation properties could be read across to MCCPs. Regarding bioaccumulation, the BCF limit is higher than that of REACH (5000 l/kg compared to 2000 l/kg). Available information on C_{14} congeners shows that lipid (but not growth) normalised BCFs are below that limit, but also above the limit if growth normalised. The alternative criterion of $K_{ow} > 5$ is fulfilled, but this should only be applied when there is no other information available; yet, monitoring data validate the concerns over MCCPs' bioaccumulation properties. Data on long-range transport was not assessed in this study. Overall, it would seem that based on available information MCCPs do not meet all the criteria for POP. It must be noted that this analysis is based on limited information and was only made as a limited exercise.

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

Table 15: PNEC calculations for MCCPs

Compartment	Starting point	AF	PNEC	Comments
$PNEC_{water}$ (freshwater)	10 µg/l from 21-day study on *D.magna*	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 *D.magna*	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 *L.variegatus & H.azteca*	10	5 mg/kg wet wt.	Registration dossier uses the dry weight PNEC
	130 mg/kg dry wt. on *L.variegatus & H.azteca*		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

Compartment	Starting point	AF	PNEC	Comments
$PNEC_{soil}$	106 mg/kg soil wet wt. on *E.fetida*	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
*: 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				

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 8** above, according to Danish EPA, in 2006 54% of MCCPs were used in PVC and 11% in rubber and other polymers. This split apparently applied to all uses of these materials and not just in EEE. Meanwhile, consultation did not reveal any uses of coatings or adhesives/sealants in EEE. Therefore, if 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). This is a conservative assumption as PVC is subject to more extensive treatment (i.e. recycling) compared to other relevant materials (e.g. rubber), thus potentially leading to higher exposures.

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. However, 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) do not fall within the scope of the recast WEEE Directive (coming into force in 2018). Cables placed on the market individually that are not part of another EEE are considered as EEE themselves[30]. The Europacable trade association further specifies that the only category of cables that fall within the remit of the recast WEEE Directive (coming into force in2018) are cables supplied directly to a final customer for various applications and are not specifically designed for EEE[31].

Whilst the above indicate that manufacturers/importers etc. of cables within EEE 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

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[30] 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).

[31] Europacable communication, available online at: http://www.europacable.com/images/Europacable_Communication_on_WEEE2_10_Oct_14.pdf (accessed on 3 August 2016).

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 cm^2;
- 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, with little (if any) flexible plastic parts used, and the main application of MCCPs identified is the use in cable sheathing. It has not been possible to identify further downstream uses, so it is assumed that cables containing MCCPs are used in the other appliances allocated within the recast WEEE Directive under the above categories indiscriminately. Apart from cables, PVC is mostly found in domestic appliances, brown goods (e.g. TV sets, radios, etc.), as well as in office and medical equipment.

5.2 Waste treatment processes applied to WEEE containing MCCPs

5.2.1 Treatment processes applied to the WEEE

Table 16 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 above, the categories are used as indicative and do not suggest applicability of the provisions of the recast WEEE Directive.

Table 16: 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. In Denmark (Danish EPA, 2014), plastics containing MCCPs for EEE applications are either landfilled, incinerated or can possibly be recycled from the recovery of waste cables, although no further information about this process is described in the report.

WEEE plastics can also be treated in third countries. The treatment processes unknown, although they may involve dumping and processing under dangerous and inefficient conditions. This is however outside the scope of the analysis.

Key points

For WEEE collected separately, the key treatment processes are:
- Manual dismantling; and
- Shredding.

For WEEE not collected separately, the key treatment processes include:
- 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 17 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, so the treatment processes of recycling ferrous metals, glass and building material are not of relevance here.

Table 17: 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									

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
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 Recovinyl, over 100,000 tonnes of PVC cable waste were collected in 2015[32]. 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;

[32] VinylPlus, available at http://www.vinylplus.eu/progress/annual-progress/2013-2, accessed on 22 July 2016.

   - 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; the process separates PVC from other materials through a process of dissolution, filtration and separation of contaminants (including MCCPs). A solvent is used in a closed loop to dissolve PVC from the waste. This makes it possible to recycle PVC waste from composite materials and recover the solvent (VinylPlus, 2014); and
- *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. The hydrocarbon part of the PVC can be used to generate syngas (or synthesis gas – an industrially useful mixture of hydrogen and carbon monoxide) which can be used as a feedstock for chemicals production (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.

However, 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, particularly China. Depending on the supply and demand balance, PVC waste sorters may choose to export their material rather than supply it to EU-based recycling companies. 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 18** summarises this stakeholder's estimations of PVC cable waste treatment.

Table 18: Industry stakeholder's estimation of methods used for PVC cable waste treatment

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

Key points	For MCCP-containing (PVC) waste that is extracted from WEEE collected separately, the key treatment processes are: • Landfilling; • Incineration; • Conventional mechanical recycling; • Non-conventional mechanical recycling; and • Export uncontrolled disposal in third countries

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 2012[33], 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 production[34].

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 million ÷ 9.1 million = 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% × 15,000 = 6,000 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% × 15,000 = 150 t/y MCCPs. This element is ignored in the analysis below.

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% × 15,000 = 1,950 t/y would end up in household waste.

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

[34] 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 exported to third countries

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% × 15,000 = 6,900 t/y MCCPs.

Key points	The fate of MCCPs in WEEE arising in the EU is assumed to be as follows: • 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

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 × 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 categories[35]. As shown in **Table 19**, overall, 69% (by weight) of separately collected WEEE is subject to shredding, while the remaining 31% is subject to manual dismantling.

Table 19: 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				

35 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 (accessed on 22 July 2016).

In other words:

- 69% × 1,200 = 828 t/y of MCCPs are present during shredding of WEEE; and
- 31% × 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 the year 2014 provide the following shares[36]:

- 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% × 1,950 = 995 t/y of MCCPs are present during landfilling of unsorted MSW; and
- 49% × 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% × 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).

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 18** 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 18**, we may consider the following split:

- 40% × 4,800 = 1,920 t/y MCCPs are exported to third countries within PVC waste;
- 25% × 4,800 = 1,200 t/y MCCPs are mechanically recycled within the EU;

[36] 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).

- 20% × 4,800 = 960 t/y MCCPs are landfilled as PVC waste within the EU; and
- 15% × 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 20: 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	✓	×	✓	✓	✓
PVC waste collection and treatment	×	✓	✓	✓	✓

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

Table 21: 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 installations may be involved in WEEE shredding across the EU	High
	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	Low (Very Low if under controlled conditions)

Lifecycle stage	Process	Description	Importance
		also result in the leaking and emission of chlorinated paraffins (Swedish EPA, 2011)	
	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: - Formulation of recycled soft PVC containing MCCPs in compounds and dry blends - Industrial use of recycled soft PVC containing MCCPs in polymer processing by calendering, 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 also 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 Commission[37] according to which the overall annual release of PM_{10} (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/dust[38];
- 0.1% of fluff/fines/dust is emitted diffusely via PM_{10} (under dry conditions, watering of the material and other measures for prevention of diffuse emissions will reduce the percentage by one order of magnitude)[39].

Using the above figures, it can be estimated that between (828 × 90% × 0.1% × 10% =) 0.075 t/y and (4,140 × 90% × 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 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/Nm^3;
- An exhaust air flow of 20,000 Nm^3/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 t MCCPs ÷ 9.1 million t WEEE = 1.65 g/kg.

Based on these assumptions the total release factor for MCCPs lost to air via residual dust emissions is 0.006 g/kg[40] with a total annual release of 828 × 0.0084 = ca. 7 kg/y.

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37 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.

38 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.

39 Based on the 2007 EC study referred to above.

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

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 × 0.09 =) 108 kg to (1,200 × 0.9 =) 1,080 kg MCCPs emitted via diffuse emissions each year; and
- (1,200 x 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: 9.6610^{-5} to 9.066×10^{-4};
- Water: nil;
- Soil: nil.

As regards the content of MCCPs in mixed cable waste, a 2003 publication noted that PVC cable accounted for 68% of total cable waste in 2003, with PE and expanded PE cable accounting for 28% (PE Europe, 2003). In the PVC fraction, chlorinated paraffins were found to represent just 1%, as shown in the figure below (PE Europe, 2003).

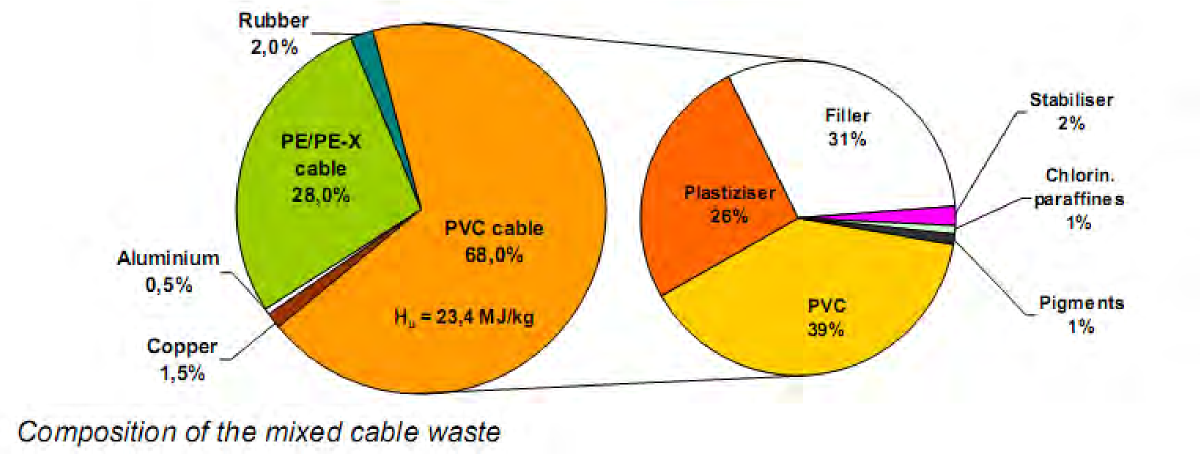

Figure 3: Composition of mixed cable waste

Source: PE Europe (2003)

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 website[41]. Details are provided below.

Table 22: 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 23: 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 recyclate
	Calendering	0.15%	See right	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.).
	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 %	

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

Source	Activity	Release factors		Other/Notes
		Air	Water	
	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% × 50% = 0.075%; and
  - Water: 0.15% × 50% = 0.075%.

The amount of MCCPs present in PVC cable waste that is subject to recycling is 1,200 t/y[42]. Therefore, the total annual releases of MCCPs from the recycling process can be estimated to be:

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

[42] Any losses arising from the shredding step are disregarded.

Notably the Recovinyl website[43] 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.

Table 24: 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 25: 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 nil.

Table 26: 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%	6.1 t/y	21.2 t/y
Incineration	2,263 t/y	0.005%	0.00285%	0.11 t/y	0.06 t/y

[43] 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).

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 27 summarises the release factors discussed above, while **Table 28** shows the total MCCP releases from each process. Finally, a material flow for MCCPs is provided in **Figure 4**.

Table 27: 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	0.0024	0.00824
Landfilling of PVC waste	0.0024	0.00824
Incineration WEEE	0.00005	0.0000285
Incineration of PVC waste	0.00005	0.0000285

Table 28: 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	1607 t/y	3.9 t/y	13.2 t/y
Landfilling of PVC waste	960 t/y	2.3 t/y	7.91 t/y
Incineration WEEE	1544 t/y	0.08 t/y	0.04 t/y
Incineration of PVC waste	720 t/y	0.04 t/y	0.02 t/y
Total		**7.73-9.37 t/y**	**22.2 t/y**

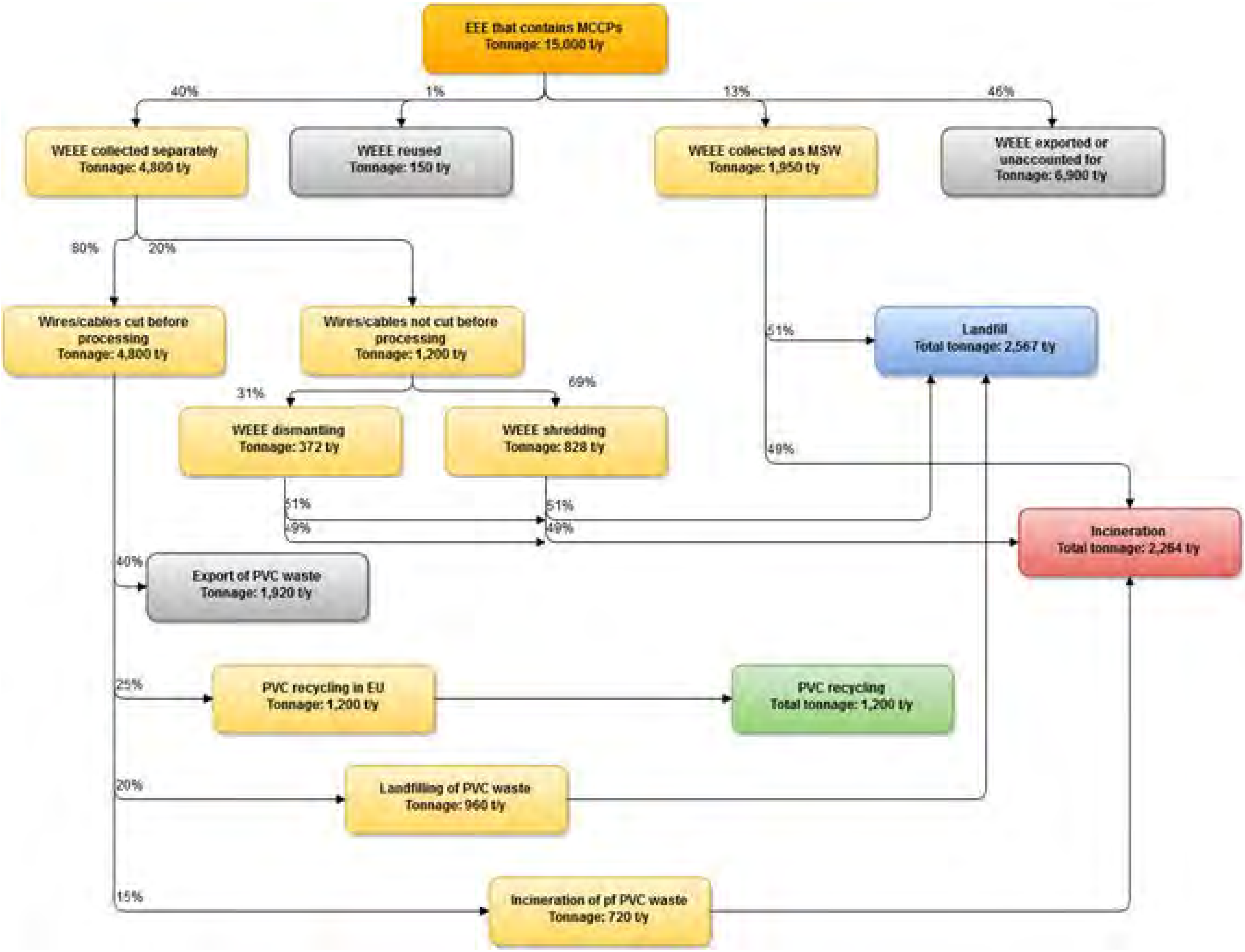

Figure 4: Flow of MCCPs in EEE within the EU

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 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 29** shows some key physicochemical information for MCCPs used in the analysis.

Table 29: 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

The following table shows the key scenario assumptions made in estimating worker exposure using the ECETOC TRA model. There are essentially 4 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.

Table 30: 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**							
Process Category (PROC)	24a	24b	24c	24a	24b	24c	1	2	3	4	8a	8b	14	15	2	3	4	6	8a	8b	14	21
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							

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 31**.

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.

Table 31: Estimated worker exposure to MCCPs during WEEE treatment – Estimates generated by ECETOC TRA

Scenario name (PROC #)	Long-term Inhalative Exposure Estimate (mg/m³)	Long-term Dermal Exposure Estimate (mg/kg/day)	Short-term Inhalative Exposure Estimate (mg/m³)	Local Dermal Exposure Estimate (µg/cm²)	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 (25b)	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

Scenario name (PROC #)	Long-term Inhalative Exposure Estimate (mg/m³)	Long-term Dermal Exposure Estimate (mg/kg/day)	Short-term Inhalative Exposure Estimate (mg/m³)	Local Dermal Exposure Estimate (µg/cm²)	Notes/comments on exposure estimates
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 [%]:

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 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 (NB. for landfilling and incineration, separate estimates are used for WEEE and PVC waste due to the different concentration of MCCPs in the relevant waste materials). 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 32 presents some selected EUSES parameters that were used as input for this assessment.

Table 32: Selected EUSES input parameters

<table>
<tr><th>Parameter</th><th colspan="3">Input</th></tr>
<tr><td>Run</td><td colspan="3">Environmental: local & regional scale
Man exposed via the environment (local & regional scale)</td></tr>
<tr><td>Assessment mode</td><td colspan="3">Interactive</td></tr>
<tr><td>Chemical class for K_{oc} – QSAR</td><td colspan="3">Predominantly hydrophobics</td></tr>
<tr><td>Bioconcentration factor in fish</td><td colspan="3">2,082 l/kg
(for a C_{15} MCCP component with 51% wt. chlorination, see Section 4.2.2)</td></tr>
<tr><td>Biodegradability</td><td colspan="3">Not biodegradable</td></tr>
<tr><td>Production volume of chemical in the EU</td><td colspan="3">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 28 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)</td></tr>
<tr><td rowspan="3">Industry category
Use category
Use pattern</td><td rowspan="3">Shredding of WEEE[44]</td><td rowspan="3">15/0: Other
47: Softeners
Waste treatment</td><td>MCCP tonnage: 828 t/y; MCCP concentration: 0.165%</td></tr>
<tr><td>Fraction of the main local source[45]: 0.0002 × 44[46] = 0.0088</td></tr>
<tr><td>Release factor to air: 0.0009066</td></tr>
</table>

[44] 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.

[45] 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.

[46] We assume 450 WEEE shredding installations. The concentration factor is thus 20,000 ÷ 450 = 44.

<table>
<tr><th>Parameter</th><th colspan="4">Input</th></tr>
<tr><td rowspan="13"></td><td rowspan="2">Shredding of PVC waste</td><td rowspan="2">15/0: Other
47: Softeners
Waste treatment</td><td>MCCP tonnage: 1,200 t/y
MCCP concentration: 1%</td><td>Fraction of the main local source: 0.1[47]</td></tr>
<tr><td colspan="2">Release factor to air: 0.0009066</td></tr>
<tr><td rowspan="2">PVC formulation</td><td rowspan="2">11: Polymers industry
47: Softeners
Polymer processing
Thermoplastics: additives, pigments, fillers
Industrial use</td><td>MCCP tonnage: As above
MCCP concentration: 10%</td><td>Fraction of the main local source: 0.4 (default for the industry and use category)</td></tr>
<tr><td colspan="2">Release factor to air: 0.0003
Release factor to water: 0.0001</td></tr>
<tr><td rowspan="2">PVC conversion</td><td rowspan="2">11: Polymers industry
47: Softeners
Polymer processing
Thermoplastics: additives, pigments, fillers
Industrial use</td><td>MCCP tonnage: As above
MCCP concentration: 10%</td><td>Fraction of the main local source: 0.4 (default for the industry and use category)</td></tr>
<tr><td colspan="2">Release factor to air: 0.00075
Release factor to water: 0.00075</td></tr>
<tr><td rowspan="3">Landfilling of WEEE</td><td rowspan="3">4: Electrical/electronic engineering industry
47: Softeners
Waste treatment</td><td colspan="2">MCCP tonnage: 1,607 t/y; MCCP concentration: 0.165%</td></tr>
<tr><td colspan="2">Fraction of the main local source: 0.0002 × 2.38[48] = 0.000476</td></tr>
<tr><td colspan="2">Release factor to air: 0.0024
Release factor to water: 0.00824</td></tr>
<tr><td rowspan="3">Landfilling of PVC waste</td><td rowspan="3">11: Polymers industry
47: Softeners
Polymer processing
Thermoplastics: additives, pigments, fillers
Waste treatment</td><td colspan="2">MCCP tonnage: 960 t/y; MCCP concentration: 10%</td></tr>
<tr><td colspan="2">Fraction of the main local source: 0.0002 × 2.38[49] = 0.000476</td></tr>
<tr><td colspan="2">Release factor to air: 0.0024
Release factor to water: 0.00824</td></tr>
<tr><td></td><td></td><td colspan="2">MCCP tonnage: 1,544 t/y; MCCP concentration: 0.165%</td></tr>
</table>

47 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 then, we use a conservative fraction of the main local source of 0.1.

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

49 Ibid.

Parameter	Input		
	Incineration of WEEE	4: Electrical/electronic engineering industry 47: Softeners Waste treatment	**Fraction of the main local source**: 0.0002 × 28[50] = 0.0056
			Release factor to air: 0.00005 **Release factor to water**: 0.0000285
	Incineration of PVC waste	11: Polymers industry 47: Softeners Polymer processing Thermoplastics: additives, pigments, fillers Waste treatment	**MCCP tonnage**: 720 t/y; **MCCP concentration**: 10%
			Fraction of the main local source: 0.0002 × 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)		

[50] We assume 600 municipal thermal treatment installations and 115 hazardous waste treatment incinerators. The concentration factor is thus 20,000 ÷ 715 = 28.

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 32** are used.

Table 33: 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 34: Local environmental PEC values for MCCP releases as estimated by EUSES

Local parameter	Unit	Shredding WEEE	Shredding PVC	Formulating PVC	Conversion PVC	Regional
Local PEC in surface water during emission episode (dissolved)	mg/L	3.38E-05	3.38E-05	5.61E-04	1.02E-03	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	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	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	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	3.00E-02
Local parameter	**Unit**	**Landfill WEEE**	**Landfill PVC waste**	**Incineration WEEE**	**Incineration PVC waste**	
Local PEC in surface water during emission episode (dissolved)	mg/L	4.92E-04	3.08E-04	5.36E-05	4.30E-05	
Local PEC in fresh-water sediment during emission episode	mg/kg ww	6.30E+00	3.94E+00	6.87E-01	5.51E-01	
Local PEC in seawater during emission episode (dissolved)	mg/L	5.04E-05	3.19E-05	6.54E-06	5.48E-06	

Local PEC in agric. soil (total) averaged over 180 days	mg/kg ww	1.08E-01	1.08E-01	1.08E-01	1.08E-01	
Daily human dose through water and food	mg/kg day	6.01E-03	5.24E-03	4.22E-03	4.15E-03	

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 5**.

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 5: 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 33** and **Table 34**) are generally lower than measured values shown in **Figure 5**. 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, some local PEC values do exceed the 5 mg/kg wet weight threshold shown in **Figure 5** (the values for the local PEC in fresh-water sediment during emission episode are 7.18 mg/kg ww for formulating PVC using recyclate 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 results[51]:

- **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 x 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);

- **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 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 organohalogens 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).

  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);

[51] 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.

- **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 C_{14} 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)[52]. 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 and conversion of PVC).

It is also worth noting that while MCCPs are not classified as a CMR substance, they are 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/m^3 but commentary is also provided in relation to the other available values (EU RAR DNEL for lactation effects of 3.0 mg/m^3 and the registration dossier DNEL of 6.7 mg/m^3).

The results of risk characterisation are presented in **Table 35**.

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

Table 35: Risk Characterisation Ratios for worker exposure to MCCPs during WEEE treatment – Estimates generated by ECETOC TRA (DNEL = 1.6 mg/m^3)

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**

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 – by dermal exposure during calendering 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 these are not used uniformly. This means that the risk can be controlled if appropriate measures are taken. Of note is that the EU RAR did not identify an unacceptable risk to workers' health under all PVC-related scenarios examined (formulation/manufacture, calendering, compounding, extrusion/moulding)

If the lactation or registration DNELs are 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. In addition, there were no human health effects which lead to a concern (a conclusion (iii)) in the EU RAR for exposure via the environment.

7.4 Risks for the environment

The results of the environmental exposure assessment will be compared to the PNECs that were calculated in the EU RAR and the REACH registration dossier, as presented in **Table 15**. The results of the comparison are shown in **Table 36**.

As can be seen in the table, some RCRs for PVC formulation and conversion, as well as one RCR value for the landfilling of WEEE are above 1, indicating a risk, although for soil and exposure of humans via the food chain the RCR values are consistently below 1.

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

- Assumptions made in the modelling are generally conservative;
- Releases from incineration (for which RCRs are below 1) could realistically be considered to be nil on the assumption of a high incineration temperature used and appropriate RMMs being in place;
- Similarly, for landfilling of MCCP-containing WEEE for which an RCR for the marine environment higher than 1 can be seen, it can be assumed that appropriate RMMs would prevent releases of MCCPs to the environment. Moreover, it may be considered that MCCPs are found within a polymer matrix and their release would not be uncontrolled. In short, RCR values for landfilling and incineration cannot be the focus of this analysis; and
- 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. Furthermore, there has been a lot of debate between ECHA and the registrants of MCCPs regarding the required test data and the representativeness of congeners used in tests, so additional care is needed when interpreting the results.

Table 36: 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	Regional values
$PEC/PNEC_{water}$ (freshwater)	1 µg/l	0.043	0.034	0.561	1.020	0.034
$PEC/PNEC_{marine}$	0.2 µg/l	0.110	0.087	1.436	2.620	0.173
$PEC/PNEC_{sediment}$	5 mg/kg wet wt.	0.027	0.023	2.920	5.450	0.023
$PEC/PNEC_{soil}$	10.6 mg/kg ww	0.010	0.012	0.356	0.657	0.082
$PEC/PNEC_{oral}$ (sec poisoning)	10 mg/kg food	0.001	0.003	0.016	0.025	0.003
Risk Characterisation Ratio	**PNEC value**	**Landfill WEEE**	**Landfill PVC waste**	**Incineration WEEE**	**Incineration PVC waste**	
$PEC/PNEC_{water}$ (freshwater)	1 µg/l	0.492	0.308	0.054	0.043	
$PEC/PNEC_{marine}$	0.2 µg/l	1.260	0.788	0.137	0.110	
$PEC/PNEC_{sediment}$	5 mg/kg wet wt.	0.252	0.160	0.033	0.027	
$PEC/PNEC_{soil}$	10.6 mg/kg ww	0.010	0.010	0.010	0.010	
$PEC/PNEC_{oral}$ (sec poisoning)	10 mg/kg food	0.001	0.001	0.0004	0.0004	

Overall, it is more realistic and appropriate to focus on the formulation and conversion of PVC which may result in RCR values above one for the freshwater, marine water and sediment compartments. 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 plasticisers[53] 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).

A recent survey report produced by the Danish Ministry of the Environment (see Danish EPA, 2014) as part of the List of Undesirable Substances review provides an in-depth overview of potential alternatives for MCCPs. Potential alternatives have also been discussed in a recent report by KemI (2015). Another significant assessment was undertaken by UK CA (2008) in the context of the transitional Annex XV restriction report.

The key potential alternatives cited within these reports (and relevant in the context of PVC EEE) have been presented in **Table 37**. 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.

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[53] 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 37: Technical feasibility/registration information for potential alternatives

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
Citrates, 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	3319-31-1	Yes	No	10 000-100 000	7	-
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. For example, **Figure 6** presents a pyramid of commonly applied fire safety standards for cables in buildings. As can be seen, a very wide variety of safety and performance standards exist.

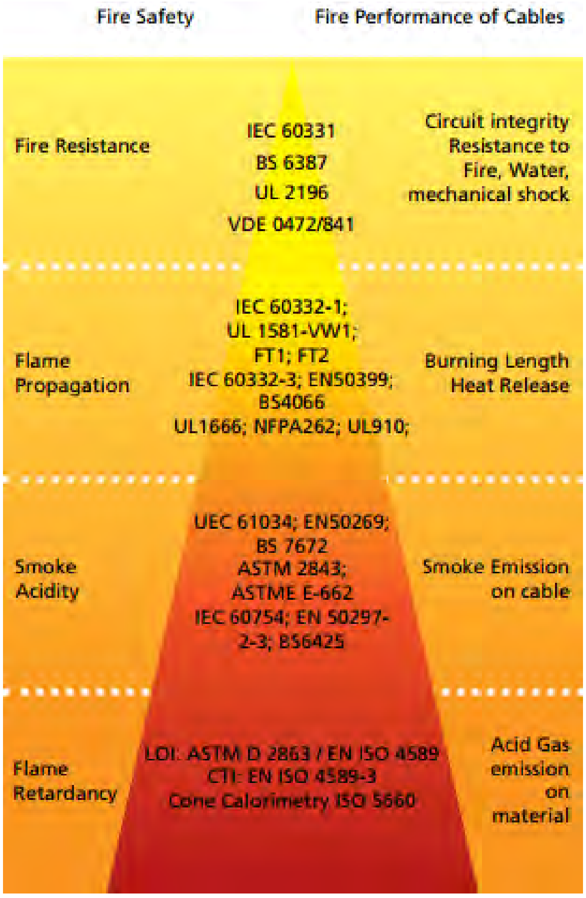

Figure 6: Pyramid of commonly applied fire safety standards for wire and cables

Source: 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 (specific information on the properties imparted by common plasticisers and additives in cable formulations has been highlighted in **Table 38**). Health and environmental impacts on these substances are further presented in **Section 8.4**.

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.

Table 38: Plasticisers for insulation and jacket compounds for wires and cables

Type	Product	Properties	Application
Primary plasticiser	DEHP	Good all-round properties	General and high performance
	DINP, DIDP	Less volatile than DEHP otherwise similar	Similar to DEHP
	Ditridecyl phthalate, TOTM	Good ageing properties extremely low volatility	High temperature compounds
Special plasticiser	Esters of dicarboxylic acid (e.g. DEHA)	Secondary plasticiser for cold resistivity	Cold resistant compounds
	Esters of phosphoric add	Primary plasticiser negative effect on photo-, thermal stability	Flame retardant formulas especially combined with antimony trioxide
	Polymeric plasticisers, polymers or elastomers	Non-migrating, resistant to oil and mineral spirits, low volatility poor plastification average cold resistivity	Compounds with high requirements on migration
	Epoxy plasticiser (epoxidised soybean oil)	Synergistic improvement of thermal and photo-stability when combined with Ca/Zn or Ba/Zn	Co-stabiliser
Extender	Chlorinated paraffin (40 - 50% Cl)	Good electrical properties, nonflammable, especially combined with antimony trioxide, negative effect on thermal and photo-stability and cold resistance	Price optimisation flame retardant
	Aromatic hydrocarbons	Limited compatibility poor light stability	Price optimisation
Source: Ernst (undated)			

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 39**, which further highlights the variety in formulations used for PVC cable compounds.

Table 39: 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 Price comparison

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 that 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 also 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 insulation[54]).

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 40: Cost comparison of MCCPs and potential alternative substances

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)
Trixylyl phosphate	25155-23-1	4850	Based on 1 available price from China	Minimum purity 99%
Triphenyl phosphate	115-86-6	2500	Based on 6 available prices from China	Minimum purity 99-99.9%
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%
Antimony trioxide	1309-64-4	5600	Based on 10 available prices from China/South Africa	Minimum purity ranges from 99 – 100%

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

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. The following factors are also of importance:

- **Loading**: 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). SFT (2009), for example, highlights that a major concern with aluminium hydroxide is the required high loading levels in order to obtain equivalent flame retardant properties as with other additives. European Parliament (2009) also highlights that the softening effect of phosphates is less efficient than that of MCCPs, so larger quantities of phosphate need to be utilised. Unfortunately, exact information in terms of MCCPs and alternatives loading capacities does not appear to be available;

- **Equipment modifications**: consideration should also be given to whether or not the implementation of a potential alternative would require cable manufacturers to modify their process equipment at significant expense. Again, 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; and

- **Re-qualification**: 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 standards[55]. 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 safety[56]) 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 market[57]. Cousins (2000) highlights that

[55] 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).

[56] 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).

[57] 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

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.

8.4 Hazardous properties of substitutes

Table 41 provides a summary of the most relevant concerns of selected alternatives used in EEE. A number of these substances have been subject to recent authoritative reviews. As such, brief summaries have been provided with reference to the relevant reports.

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 C_{20-30} 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 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.

Di-isononyl phthalate (DINP), as highlighted by Umweltbundesamt (2014), DINP was assessed within the European Risk Assessment series. Based on the current legislation the use of DINP in toys and childcare articles which can be placed in the mouth is restricted. This measure was re-evaluated in 2013 by ECHA and no alterations of existing restriction of DINP and DIDP are foreseen related to entry 52 in Annex XVII to the REACH Regulation. DINP possess hepatotoxic effects and the most sensitive endpoint is the hepatotoxic effect of DINP. There are some disagreements related to its anti-androgenic potential.

Di-isodecyl phthalate (DIDP), as highlighted by Umweltbundesamt (2014), was assessed within the European Risk assessment series. Based on the current legislation the use of DIDP in toys and child care articles which might be placed in the mouth is restricted. This measure was re-evaluated in the year 2013 by ECHA and no alteration of existing restriction of DINP and DIDP foreseen related to entry 52 in Annex XVII to REACH.

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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).

Table 41: Summary of most relevant hazard concerns for identified alternatives

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 hepatis together with other signs of hepatotoxicity in rats. Disagreement regarding relevance of spongiosis hepatis in humans. Concerns over endocrine disruption potential (anti-androgenic effects)	No toxic effects towards fish, invertebrates or algae	No classification	Umweltbundesamt (2014)
DIDP	68515-49-1 / 26761-40-0	Significant increases of incidence of spongiosis hepatis together with other signs of hepatotoxicity in rats. Disagreement regarding relevance of spongiosis hepatis in humans. Reprotoxic effects. Decrease in survival incidences (NOAEL: 33 mg/kg bw/day)	Low bioaccumulation properties	No classification	Umweltbundesamt (2014)
DEHA	103-23-1	DEHA has been suspected of having effects on the male reproductive system because it shares similarities in chemical structure and metabolism with DEHP	Not expected to be persistent in air, water, soil or sediment. Not expected to bioconcentrate or bioaccumulate in aquatic organisms	No classification	Tukes (2013) Environment Canada/ Health Canada (2011)
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	No classification	ECHA (2012)

Substance name	CAS Number	Human health concerns	Environmental health concerns	Harmonised (HC) classification	Source / additional information
Trimellitates e.g: Tris-2-ethylhexyl (TOTM)	3319-31-1	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	-	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	Reproductive toxicant	-	Repr. cat. 1B	ECHA (2013)
Triphenyl phosphate	115-86-6	Chronic toxicant with effects on liver	Readily biodegradable, toxic to aquatic organisms	No classification	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	1241-94-7	Risks from consumer products not identified	No risk identified; not a PBT/vPvB	No classification	Arcadis & EBRC (2011) ECHA website
Antimony trioxide	1309-64-4	Potential human carcinogen and reproductive toxicant	Not readily biodegradable, low to moderate bioaccumulation potential	Carc. cat. 2	Umweltbundesamt (2014b) BAuA (2016) KemI (2015)

DEHA was added to the CoRAP list in 2013 and is to be evaluated by the Finnish Safety and Chemicals Agency (Tukes) in 2017. In the justification document for the selection of a CoRAP substance (see Tukes (2013)), the authors note that DEHA has been suspected of having effects on the male reproductive system because it shares similarities in chemical structure and metabolism with DEHP. DEHA has also produced some effects on development and reproduction in reproductive toxicity studies. DEHA is not expected to be persistent in air, water, soil or sediment. With regard to environmental concerns, the substance was subject to a screening assessment report (see Environment Canada/Health Canada (2011)), which concluded that its low water solubility, as well as its tendency to partition to particles and lipids (fat) of organisms, indicates that it will predominantly reside in soil and sediment when released to the environment. Nevertheless, DEHA appears to have a low bioaccumulation potential, likely due to rapid metabolism. Both empirical and modelled data demonstrate that DEHA biodegrades in water and that it is also not expected to persist for long periods in air, sediment, or soil. Acute toxicity studies generally report no effects to aquatic organisms at the water solubility limit, but there is potential for chronic toxicity, particularly for invertebrates.

ATBC, as highlighted by ECHA (2012) in Öko-Institut (2014b), has low acute toxicity, low or slight sensitising, no mutagenic activity and no reproductive effects. Some signs of neurotoxicity were observed. ATBC was not found to be toxic to reproduction. The critical NOAEL is 100 mg/kg based on reduced body weight gain and increased liver weight. As for environmental hazards, ATBC has been found to be readily biodegradable as well as ultimately biodegradable; however, there are indications for bioaccumulation potential as well as strong sorption properties i.e. low mobility in soil (BCF = 250 and a Koc = 1,800 have been calculated for ATBC based on a water solubility of 5 mg/L). There is potential for aquatic toxicity.

TOTM was initially added to the CoRAP list in 2012. According to ECHA (2014b), further information is required in order to ascertain whether the substance constitutes a risk regarding environment/suspected PBT, exposure/wide dispersive use and 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).

Aluminium hydroxide was assessed in the Arcadis and EBRC (2011) report regarding the identification and evaluation of data on flame retardants in consumer products. The report concluded that the substance did not pose a risk to human health. However, data gaps existed in terms of environmental hazards.

Cresyl diphenyl phosphate was assessed in the Arcadis and EBRC (2011) report regarding the identification and evaluation of data on flame retardants in consumer products. The report identified risks for both human health (consumer) and the environment. KemI (2015) highlights that the substance is a chronic toxicant with effects on liver, kidney, blood as well as fertility.

Tricresyl phosphate was assessed in the Arcadis and EBRC (2011) report regarding the identification and evaluation of data on flame retardants in consumer products. The outcome of the assessment was inconclusive in terms of risk to human health (consumer) and the environment.

Trixylyl phosphate is currently on the Candidate List of Substances of Very High Concern for Authorisation, under REACH. The substance has a harmonised classification and a category 1b reproductive toxicant and, as such, is not considered to be a suitable alternative for MCCPs.

Triphenyl phosphate was assessed in the Arcadis and EBRC (2011) report regarding the identification and evaluation of data on flame retardants in consumer products. The report identified risks for both human health (consumer) and the environment, due to data gaps. Indeed, KemI (2015) identified the substance as a chronic toxicant with effects on the liver.

Isodecyl diphenyl phosphate was assessed in the Arcadis and EBRC (2011) report regarding the identification and evaluation of data on flame retardants in consumer products. Risks were identified for both consumer health and the environment.

2-ethylhexyl diphenyl phosphate (also known as ODP) was assessed in the Arcadis and EBRC (2011) report regarding the identification and evaluation of data on flame retardants in consumer products. For consumer exposure via inhalation from the use of the substance in cables, the RCR was found to be marginally lower than 1. The environmental risk RCRs were also found to be lower than 1. The substance does not have harmonised classification and it is worth noting that a dossier evaluation decision dated 24 Jun 2014 requested that the registrants submit the hazard classification of ODP for Aquatic Toxicity 1 and Aquatic Toxicity 2. Several notifiers have made C&L classifications for Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410). ODP has also been subject to a PBT hazard assessment by the UK authorities and this has concluded that it is not a PBT or a vPvB substance[58].

Antimony trioxide was subject to a European Union Risk Assessment Report in 2008. The substance was reviewed alongside MCCPs in the KemI (2015) assessment of the risk reduction potential of hazardous substances in EEE on the EU market. Antimony trioxide is considered to be a threshold carcinogen with a NOEL of 0.5 mg/m^3 for carcinogenicity via inhalation. It is also on the CoRAP, being assessed by the German Federal Institute for Occupational Safety and Health (BAuA). In the justification document for the selection of a CoRAP substance (see BAuA (2016)), the authors highlight the current Carc. 2, H351 substance classification, noting that due to the deviations from the OECD guidelines and the critical shortcomings in all three chronic inhalation studies, the US National Toxicology Program has embarked upon a testing programme leading to a new, full 2-year bioassay. The authors add that depending on the outcome of the NTP study a carcinogenicity reclassification may be necessary and that it is currently unclear if a risk for workers arises and further risk management measures need to be implemented. The substance is not considered a suitable alternative for MCCPs.

8.5 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

[58] 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).

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 42**.

Table 42: 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

Supply chain stakeholder category	Number of EU companies	Number of potentially exposed workers	Sources and notes
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 workers across the EU cable industry)	Europacable estimated that around 235 European companies would have to include RoHS specific aspects in the conformity declarations (bioIS & ERA Technology, 2012)
PVC waste recyclers (shredders)	52	250-780	The Recovinyl website[59] 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).

[59] 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).

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

9.2 Economic impacts

9.2.1 Impact on chemicals suppliers

Impact on MCCP manufacturers

9.1.1.1.1 Economic 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 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 (see **Table 40**) suggests an average price of €850/t, meaning that the value of the affected market could be a maximum of €850 × 15,000 = ca. €12.8 million.

9.1.1.1.2 Economic 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 40**, the price of LCCPs per tonne is estimated to be ca. 24% higher than MCCPs, or €1050 vs. €850 per tonne).

Impact on PVC manufacturers

9.1.1.1.3 Economic 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.

9.1.1.1.4 Economic 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.

Impact on manufacturers of alternatives

9.1.1.1.5 Economic costs under the Restriction Scenario

No additional costs can be envisaged.

9.1.1.1.6 Economic 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. Details are provided in the grey box below.

Replacement ratios for MCCPs, phthalates and phosphates (Weil, et al., 2006)
"*…Cost savings can also be achieved by replacing part of the antimony oxide or phosphate plasticizer in a PVC formulation by chlorinated paraffin. For example, a formulation of 50 parts per hundred resin based on 100 parts of PVC (phr) dioctyl phthalate and 8 phr antimony oxide can be replaced with 40 phr dioctyl phthalate, 12 phr chlorinated paraffin, and 4 phr antimony oxide, with similar performance and some cost savings. Likewise, a formulation of 30 phr calcium carbonate, 3 phr antimony oxide, 15 phr dioctyl phthalate, and 35 phr octyl diphenyl phosphate can be replaced, as suggested by Dover, with 30 phr calcium carbonate, 3 phr antimony oxide, 25 phr octyl diphenyl phosphate, and 12 phr chlorinated paraffin with cost savings but substantially equivalent physical properties.*
To avoid migration and exudation, the level of chloroparaffin must be limited, the limit depending on the primary plasticizer. With dioctyl phthalate, the chloroparaffin) should not exceed 20phr whereas with diisononyl phthalate, the chloroparaffin should not exceed 16 phr. Higher levels of chloroparaffin can be used when a primary plasticizer is an aryl phosphate."

Table 43 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 43: Example fire-retarded PVC formulations with or without MCCPs (all figures in phr)

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)				

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.

9.2.2 Impact on cable manufacturers

Economic costs under the Restriction Scenario

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 **Table 10**).

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

9.1.1.1.7 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, 5,000 t/y MCCPs) by:

- LCCPs, with a replacement ratio of 1:1;
- DINP, on the basis of the composition of Formulations A and A' in **Table 43**; and
- 2-Ethylhexyl diphenyl phosphate and DINP, on the basis of the composition of Formulations B and B' in **Table 43**.

Replacement by LCCPs: based on **Table 40**, the market price difference between MCCPs and the LCCPs is on average €200/t (the source of the data is the Alibaba.com[60] online marketplace). For a consumption of 5,000 t/y MCCPs, the cost increase could be €200 × 5,000 = €1 million/y.

Replacement by DINP (plus antimony trioxide): based on **Table 43**, 12 phr of MCCPs would be replaced by 11 phr DINP and 4 phr antimony trioxide. Thus, 5,000 t/y MCCPs would be replaced by 4,583 t/y DINP and 1,667 t/y antimony trioxide. The original cost of

[60] Available at https://www.alibaba.com/.

€850 × 5,000 = €4.25 million/y would be replaced by a cost of €1,650 × 4,583 + €5,600 × 1,667 = €16.9 million/y. The overall cost increase would be ca. €12.6 million/y.

Replacement by phosphate (and phthalate): based on **Table 43**, 12 phr of MCCPs would be replaced by an extra 10 phr 2-ethylhexyl diphenyl phosphate and 16 phr DINP. Thus, 5,000 t/y MCCPs would be replaced by 4,167 t/y 2-ethylhexyl diphenyl phosphate and 6,667 t/y DINP. The original cost of €850 × 5,000 = €4.25 million/y would be replaced by a cost of €2,450 × 4,167 + €1,650 × 6,667 = ca. €21.2 million/y. The overall cost increase would be ca. €17 million/y.

The overall additional cost for the replacement of all 15,000 tonnes of MCCPs would therefore be: €1 million + €12.6 million + €17 million = ca. €31 million/y. This 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.

9.1.1.1.8 Cost of process and equipment adaptations to the chosen alternative

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 DEHP[61] (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 would be €31 million × (15÷85) = €5.5 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. €1.2 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 account[62]. 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 (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.

[61] 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.

[62] 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.

9.1.1.1.9 *Cost of re-qualification of reformulated products*

No information is available that would allow us to describe and quantify this cost to cable manufacturers.

Economic benefits under the Restriction Scenario

No tangible economic benefits can be envisaged for cable manufacturers given that MCCPs is currently used due to its combination of properties (plasticiser and flame retardant) and lower cost in comparison to primary plasticisers and other flame retardants. Nevertheless, it can be envisaged that cable manufacturers might aim to pass their overall increased manufacturing costs to their customers.

9.2.3 Impact on EEE manufacturers

Economic costs under the Restriction Scenario

The magnitude of costs 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 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 €32.2 million/y for the first five years and €31 million/y 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 €32.2 million × 59% = €19 million/y over the first five years and €31 million × 59% = €19.3 million/y thereafter, with the rest being borne by non-EU manufacturers of EEE[63]. 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 2.4.3) could be found within 9.1 million tonnes of EEE (see Section 5.3.1). Therefore, the total estimated cost of €36.5 million could be equivalent to €0.004 per kilogram of EEE (whether it is manufactured inside or outside the EU).

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[63] 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.

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).

Economic benefits under the Restriction Scenario

No tangible economic benefits can be envisaged for EEE manufacturers. It can be envisaged that EE manufacturers might aim to pass their increased manufacturing costs to the consumer; however, the economic costs described above are low so EEE manufacturers might decide to absorb them.

9.2.4 Impact on EEE users

Economic costs under the Restriction Scenario

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 €0.004 per kg EEE calculated above, would produce an additional cost of €0.24. 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/kg[64];
- The additional cost for this item of EEE due to the replacement of MCCPs would be 0.2 × €3.4 = €0.68.

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

Economic benefits under the Restriction Scenario

No tangible economic benefits can be envisaged for the consumer.

9.2.5 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.

9.2.6 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, as suggested by Euro Chlor, which

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[64] In an example provided earlier, 5,000 tonnes of MCCPs are replaced by a combination of DINP and 2-ethylhexyl diphenyl phosphate with an additional cost of €17 million. Therefore, the additional cost per tonne of MCCPs replaced is ca. €3,400.

represents manufacturers of chloro alkanes. Euro Chlor makes the following key points on the analysis of chloro alkanes (Euro Chlor, 2015):

- It is not currently possible to accurately quantify individual chloro alkane components, although state-of-the-art techniques can qualitatively identify groups of chloro alkane isomers by carbon chain length and chlorination level;

- Currently, the most commonly used method of detection and quantification used in the literature is either high or low definition gas chromatography followed by electron capture negative ion mass spectrometry (GC-ECNI-MS). Whilst popular, this method has difficulty in accurately separating different congeners with the same chlorine number, and with the detection of congeners containing low numbers of chlorine atoms ($\leq C_{15}$). The state-of-the-art in chloro alkane detection is 2-dimensional gas chromatography combined with electron capture detection (GCxGC-ECD). The GCxGC separation method is able to qualitatively identify groups of chloro alkane isomers by carbon chain length and chlorination level, although this is very difficult due to the complex nature of the groups of chloro alkanes;

- There is low response of chloro alkanes in detection systems; and

- There is a lack of consistency in inter-laboratory studies.

Sample analysis needs to take place in a laboratory at a cost that is currently unknown. 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)).

9.3 Human health and environmental impacts

9.3.1 Human health impacts

An overview of the benefits to human health under the Restriction Scenario is represented in **Table 44**.

Table 44: 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	Costs and benefits to human health	
MCCPs manufacturers	<9	Unknown	Low benefit	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	Low benefit	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	Neutral	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 exhalative exposure of workers of 1.40 mg/m^3 for PROC 24c *(High (mechanical) energy work-up of substances bound in materials and/or articles - pt > mp - High Fugacity*; see **Table 31**). The risk characterisation has not raised any concern (see **Table 35**)

Supply chain stakeholder category	Number of EU companies	Number of potentially exposed workers	Costs and benefits to human health	
PVC waste recyclers (shredders)	52	250-780	Benefit	Modelling undertaken for this report shows a maximum long-term exhalative exposure of workers of 2.80 mg/m^3 (*High (mechanical) energy work-up of substances bound in materials and/or articles - pt > mp - High Fugacity*; see **Table 31**). The risk characterisation has raised some concern over inhalation exposure (see **Table 35**). 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 31**). The risk characterisation has raised some concern over inhalation exposure (see **Table 35**). 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	Neutral	No discernible exposure is expected. An assessment of exposure and risk has not been undertaken in this report
Incinerators	715	Unknown	Neutral	No discernible exposure is expected. An assessment of exposure and risk has not been undertaken in this report
Consumers/general public	-	500 million citizens	Neutral	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 benefits to 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 recyclate. 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.

9.3.2 Environmental impacts

An overview of the benefits to the environment under the Restriction Scenario is represented in **Table 45**. 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. Releases from landfills and incinerators have been calculated through modelling but if operated under the strict conditions prescribed by regulation, releases of MCCPs from the PVC matrix should be eliminated;
- The overall releases of MCCPs that would be eliminated would amount to over 4 tonnes per year; and
- Elimination of releases of MCCPs from these activities would also mean the elimination of releases of SCCPs which are to be found in commercial MCCPs products.

Table 45: Summary of environmental impacts along the supply chain under the Restriction scenario

Supply chain stakeholder category	Number of EU companies	Costs and benefits to the environment	
MCCPs manufacturers	<9	Low benefit	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	No MCCP release but potential release of alternatives during their manufacture. Some concerns over their hazards exist (see **Table 41**), namely: LCCPs are potentially persistent and bioaccumulative, DIDP shows low bioaccumulation effects, TOTM is a potential PBT/vPvB substance, cresyl diphenyl phosphate shows aquatic toxicity, antimony trioxide is not readily biodegradable and shows low to moderate bioaccumulation potential
PVC manufacturers	40 different plants spread over 21 sites	Neutral	No MCCPs emissions
Masterbatch manufacturers	14	Uncertain effect	Not explicitly assessed in this report. Expect similarities to PVC formulation (see below)

Supply chain stakeholder category	Number of EU companies	Costs and benefits to the environment	
Cable manufacturers	235	Neutral	Not assessed in this report. Unlikely that any significant MCCPs emissions occur
WEEE treatment installations (shredding)	450	Benefit	Risk Characterisation Ratios calculated in this report do not show an unacceptable risk. However, an estimated **0.75 tonnes** of MCCPs are expected to be released to air each year
PVC waste recyclers (shredders)	52	Benefit	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
PVC formulation	<50	Benefit	Risk Characterisation Ratios calculated in this report show a concern for **marine water** and **sediment**. However, an estimated **0.36 and 0.12 tonnes** of MCCPs are expected to be released to air and water respectively each year
PVC conversion		Benefit	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
Landfills	8,400	Neutral	Under normal operating conditions, releases of MCCPs to the environment should be adequately controlled. Modelling results suggest that **6.2 tonnes** of MCCPs are released to air and **21.1 tonnes** are released to water each year
Incinerators	715	Neutral	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

The PBT properties of some congeners of MCCPs should be considered (as well as those of SCCPs which may be contained in commercial MCCPs products), particularly in respect of the dangers of their build-up within the environment. For PBT substances the major concern is that accumulation of such substances in the food chain may result in effects often difficult to predict in the long term. **Table 46** overleaf provides a summary of the nature of the risk concerns in relation to ecosystem services. Note that supporting services are not considered since they underpin the other service categories thus their inclusion could result in double counting.

Table 46: Qualitative Assessment of Environmental Impacts – Ecosystem Services

Service	Potential impact (if relevant)	Direction of impact
Provisioning services		
Provision of food	Potential impact on fisheries and other food sources. MCCPs are highly toxic to aquatic organisms both acutely and after repeated exposure, having long-term effects. MCCPs are present in marine fish, terrestrial organisms and birds of prey. MCCPs have also been found in mothers' and cows' milk	Negative
Provision of fibre and fuel (includes wood, peat, fibre, etc.)	Not relevant	None identified
Provision of water (i.e. water supply)	Not relevant (but note the persistence of MCCPs)	None identified
Provision of bio-chemicals, medicines and pharmaceuticals	Not relevant	None identified
Provision of ornamental products (e.g. shells, flowers, etc.)	Not relevant	None identified
Genetic resources (including genes and genetic information for animal and plant breeding; also diversity of life)	Potential for impacts on biodiversity due to long-term effects of MCCPs on aquatic organisms. MCCPs are present in marine mammals (including top predators such as porpoise and fin whale).	Negative
Regulating services		
Air quality regulation (ecosystems help regulate air quality)	MCCPs are released to the atmosphere during waste management. The atmospheric half-life of MCCPs has been estimated at 1-2 days and monitoring studies have ubiquitously detected MCCPs in biota, including fish, marine mammals, terrestrial organisms and birds	Negative
Climate regulation (including carbon sequestration and storage)	Not relevant	None identified
Water regulation (including water availability, flooding, etc.)	Not relevant	None identified
Erosion regulation (incorporating soil erosion and degradation)	Not relevant	None identified
Water purification (habitats may filter water, removing contaminants)	MCCPs (at least some congeners) are persistent in the aquatic environment. Monitoring evidence suggests that MCCPs with chlorine contents of around 55% by weight may persist for a long time in sediments	None identified
Pest and disease regulation (including control of invasive species and aliens)	Not relevant	None identified
Pollination	Not relevant	None identified
Natural hazard regulation (including storms, floods, landslides, etc.)	Not relevant	None identified
Cultural services		
Cultural heritage (includes landscape and heritage value)	Not relevant	None identified
Aesthetics (including non-material benefits gained from ecosystems)	Possible impacts on health of or loss in species of symbolic importance and important for ecotourism	Negative
Science and education	Not relevant	None identified

9.4 Social impacts

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.

Finally, no impact on the welfare of consumers is expected as consumers are unlikely to lose satisfaction out of the use of EEE that contains PVC cabling after the replacement of MCCPs; the performance of the end products would not be affected.

9.5 Comparison of socio-economic impacts and impacts on human health and the environment

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 47**. The overall quantifiable costs are €32.2 million per year over the first five years and €31 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 €0.004 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.

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 cost of the proposed restriction after year 5 would be €31 million ÷ 4.12 tonnes = ca. €7,500 per kilogram of MCCPs released.

Table 47: Comparison of socio-economic costs and benefits for human health and the environment from a restriction on the use of MCCPs

<table>
<tr><th rowspan="2">Supply chain link</th><th colspan="3">Economic costs</th><th colspan="2">Human health and environmental benefits</th><th rowspan="2">Difference between Restrictions and Baseline Scenarios (comparison of costs and benefits)</th></tr>
<tr><th>Description</th><th colspan="2">Value</th><th>Human health benefits</th><th>Environmental benefits</th></tr>
<tr><td>MCCPs manufacturers</td><td>Loss of sales of MCCPs but potentially (some) of LCCPs new sales</td><td colspan="2">Up to €12.8 million/y (probably less)</td><td>Low benefit to workers (EU RAR identified no concern)</td><td>Low benefit to environment (EU RAR identified no concern)</td><td rowspan="6">Overall economic costs of at least €36.5 million/y shared spread between cable manufacturers, EEE manufacturers (EU & non-EU) ad consumers.

Overall human health and environmental benefits include lower worker exposures ad avoidance of the release of 4.12 tonnes of MCCPs per year</td></tr>
<tr><td>PVC manufacturers</td><td>PVC may be replaced by other polymers in cable formulations</td><td colspan="2">Not quantified</td><td>No changes</td><td>No changes</td></tr>
<tr><td>Alternatives manufacturers</td><td>Generation of income from new sales of alternatives</td><td colspan="2">Unknown but it would at least balance the losses of MCCPs manufacturers and PVC manufacturers</td><td>Several of the alternatives raise health concerns (particularly, antimony trioxide, trixylyl phosphate, DEHA, phthalates)</td><td>Several of the alternatives raise concerns over PBT properties (LCCPs, TOTM, antimony trioxide) or toxicity (cresyl diphenyl phosphate)</td></tr>
<tr><td>Masterbatch manufacturers/ Cable manufacturers</td><td>Loss of profit from increased cost of plasticiser/flame retardant. Cost of process and equipment adaptation</td><td colspan="2">€5.5 million investment costs
€31 million/y for alternatives</td><td>Not assessed in this report. Any exposure to MCCPs might be replaced by exposure to alternatives</td><td>Not assessed in this report. Any releases of MCCPs might be replaced by releases of alternatives</td></tr>
<tr><td>EEE manufacturers</td><td>Loss of profit from higher cost of MCCP-free PVC cabling.
Increased cost of testing</td><td>Years 0-4
EU-based: €19 million/y
Non-EU based: €13.2 million/y</td><td>Year 5 onwards
EU-based: €18.3 million/y
Non-EU based: €12.7 million/y</td><td>Not assessed in this report. No real impact envisaged</td><td>Not assessed in this report. No real impact envisaged</td></tr>
<tr><td>Testing laboratories</td><td>Increased use of their sample testing services</td><td colspan="2">Revenues will counterbalance losses for EEE manufacturers</td><td>No impact</td><td>No impact</td></tr>
</table>

Supply chain link	Economic costs		Human health and environmental benefits		Difference between Restrictions and Baseline Scenarios (comparison of costs and benefits)
	Description	**Value**	**Human health benefits**	**Environmental benefits**	
WEEE shredders	No impact	No impact	Exposure of workers raises no concern (RCR<1)	Avoidance of MCCPs releases: 0.75 t/y to air, as well as SCCPs releases (present in technical MCCP products)	
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, as well as SCCPs releases	
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 significant[65]. SMEs may have limited resilience when faced with increased raw material and regulatory compliance costs.

9.6 Input from consultation with industry stakeholders

The extent of contributions made by industry stakeholders to the analysis presented above has unfortunately been well below expectations. This might give an indication of the low scale of difficulties that industry might face following a restriction on the use of MCCPs but this could perhaps be an oversimplification of the actual situation.

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). Thus time-limited derogations might need to be considered in this context.

Finally, it is also worth noting one consultee's position that MCCPs and their potential risks would be best dealt with under the REACH Regulation rather than the RoHS Directive. The consultee argued that MCCPs' hazardous properties that would warrant regulatory intervention have not been clearly established yet. If this would be done, the substance would be added to the REACH Candidate List and would be best controlled under the REACH Regulation rather than the RoHS2 Directive. A restriction under the RoHS2 Directive ahead of REACH would be a very costly measure, according to the consultee's submission. More specifically, the consultee has pointed out that in the case of a RoHS restriction, the search for alternatives would be borne by relatively few economic operators: if EEE manufacturers have to replace the substance by themselves, testing of the alternatives on their properties and durability would take longer and the cost would be shared by a smaller pool of stakeholders. In the case of a REACH restriction, (a) upstream operators would also have to look for alternatives to the restricted applications, and (b) a wider pool of downstream users would

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[65] 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).

have to engage in the search for an alternative and thus could share their experience through trade associations, etc. thereby limiting the cost for research and testing.

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 associate 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 C_{14} congeners with 40-50% wt. chlorination meet the criteria for very bioaccumulative substances (BCF > 5000), while C_{14} congeners with 50-55% wt. chlorination meet the criteria for bioaccumulative substances (BCF > 2000); C_{14} with 55-65% wt. chlorination are a borderline case.

MCCP use is not explicitly restricted at Community level (only some measures relating to MCCPs at national level (Germany, Norway) are in place). The focus of the regulators has, so far, been on SCCPs, which have PBT properties, are suspected carcinogens and have bene under scrutiny in the context of long range transboundary air pollution. However, the presence of SCCPs in technical MCCPs products 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 being of relevance to 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 ECETOC TRA (v3) and EUSES (v2.1) have been used for the estimate of releases and exposure to MCCPs. The assumed tonnage of MCCPs may well be an underestimate.

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 WEE treatment installations, PVC recyclers and PVC compounders is estimated at 3,750-8,750, as shown in **Table 42**.

Through a series of assumptions on the fate of this EEE at the end of its useful 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. If presumed releases from landfilling and incineration are excluded, a total of 4.12 tonnes MCCPs are released to the EU environment every year. 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 that what has been estimated in this report.

By way of comparison, the UK Annex XV restriction report estimates that the total EU emissions of MCCPs to air in 2006 were ca. 132 tonnes and to water ca. 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 only for a small number of the scenarios considered and only when the most stringent DNEL for carcinogenicity of 1.6 mg/m^3 that is presented in the EU RAR. Only for shredding of PVC cable waste (PROC24c) and conversion of PVC recyclate (PROC6) inhalation and dermal exposure respectively lead to RCR values above 1 and an overall RCR of 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. On the other hand, if less stringent RMMs than those assumed (e.g. presence of LEV when recycling PVC waste) are applied during recycling processes, it is likely that the risks through inhalation exposure would not be adequately controlled.

With regard to environmental risks, some RCRs for PVC formulation and conversion, as well as one RCR value for the landfilling of WEEE are above 1, indicating a risk, although all scenarios for soil and exposure of humans via the food chain the RCR values are consistently below 1. RCR values above 1 have been identified for:

- Formulation of PVC: marine water (1.44) and sediment (2.92);
- Conversion of PVC: freshwater (1.02), marine water (2.62) and sediment (5.45); and
- Landfilling of WEEE: marine water (1.26).

For landfilling of MCCP-containing WEEE, for which an RCR for the marine environment higher than 1 can be seen, it can be assumed that appropriate RMMs should prevent releases of MCCPs to the environment. Moreover, as MCCPs are found within a polymer matrix it may be assumed that their release would not be uncontrolled. Thus, the main environmental concern relates to the use of PVC recyclate in the manufacture of PVC articles.

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 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;
- 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.

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, aluminium hydroxide and antimony trioxide. 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 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 will 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) but would result in a significant reduction, 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 RoHS2 Directive. On the basis of limited information, the quantifiable portion of the costs has been found to be up €5.5 million in investment costs and €31 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, 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, the administrative burden for enforcing a restriction on the use of MCCPs could be significant, given the difficulties associated with the detection and quantification of MCCPs.

10.5 Conclusions

The key points of this analysis are:

- Some MCCPs appear to meet the criteria for PBT substances and commercial (technical) MCCP products may contain SCCPs;
- There may be risks associated with the continued use of MCCPs in EEE applications, primarily to the environment, that need to be controlled;
- MCCPs may be released from shredding and recycling operations as well as uncontrolled waste management (releases from landfill should be possible to adequately control);
- 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. Some alternatives are accompanied by their own hazard-related concerns; and
- 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.

As the use of SCCPs is phased out the production and use of MCCPs and other CP mixtures 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.

11 Glossary

AEL	Average emission levels
AOH	Aluminium oxide-hydroxide
APP	Ammonium polyphosphates
ATBC	Acetyl tributyl citrate
ATH	Aluminium trihydroxide
ATP	Adaptation to Technical Process
BCF	Bio-concentration factor
BOD	Biological oxygen demand
BREF	Best Available Techniques reference documents
CA	Competent Authority
CAS numbers	Chemical Abstract Service numbers
CDP	Cresyl diphenyl phosphate
Cl	Chlorine
CLP	Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging
CoRAP	Community Rolling Action Plan
CRC	Chemical Review Committee
DEHA	Bis(2-ethylhexyl) adipate
DEHP	Bis(2-ethylhexyl)phthalate
DINP	Diisononyl phthalate
DNEL	Derived No Effect Level
EC numbers	European Community numbers
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
EEA	European Environment Agency
EEE	Electric and Electronic Equipments
EPA	Environmental Protection Agency
EPDM	Poly-Ethylene-Diene Rubbers
ESR	Existing Substances Regulation (EEC) 793/93
EU RAR	EU Risk Assessment Report
EVA	Ethylene-Vinyl Acetate
GC-LRMS Spectrometry	Gas Chromatography Coupled to Low Resolution Mass

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	Phosporous, 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
TOTM	Tris (2-ethylhexyl) trimellitate
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

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