Öko-Institut e.V.
Institut für angewandte Ökologie
Institute for Applied Ecology

ROHS Annex II Dossier MCCPs.

Restriction proposal for substances in electrical and electronic substances equipment under RoHS

Report No. 4:
Medium- chained chlorinated paraffins (MCCPs) – Alkanes, C14-17, chloro
EC Number(s): 287-477-0
CAS Number(s): 85535-85-9

05/12/2019

Head Office Freiburg
P.O. Box 17 71
79017 Freiburg
Street address
Merzhauser Strasse 173
79100 Freiburg
Tel. +49 761 45295-0

Office Berlin
Schicklerstrasse 5-7
10179 Berlin
Tel. +49 30 405085-0

Office Darmstadt
Rheinstrasse 95
64295 Darmstadt
Tel. +49 6151 8191-0

info@oeko.de
www.oeko.de

Table of Contents

List of Tables

Abbreviations

CAS number	A CAS Registry Number, also referred to as CASNR or CAS Number, is a unique numerical identifier assigned by Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACh)
CoRAP	Community Rolling Action Plan
DINP and DIDP	Diisononyl phthalate
DNELs	Derived No Effect Level
EC number	The European Community number (EC Number) is a unique seven-digit identifier that was assigned to substances for regulatory purposes within the European Union by the European Commission.
ECETOC TRA model	European Centre for Ecotoxicology and Toxicology of Chemicals’ Targeted Risk Assessment
EEE	Electrical and Electronic Equipment
EINECS	European Inventory of Existing Commercial Chemical Substances
EPA	Environmental Protection Agency
EU RAR	EU Risk Assessment Report
KEMI	Swedish Chemicals Agency
LCCPs	Long-chained chlorinated paraffins
LOAEL	Lowest Observed Adverse Effect Level
MCCPs	Medium-chained chlorinated paraffins
MSDS	Material safety data sheet
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
OEL	Occupational exposure limits
OH radicals	Hydroxyl radical
P & B properties	Physico-chemical properties
PE, HDPE	Polyethylene, High density polyethylene
PEC	predicted environmental concentrations
PNEC	Predicted No Effect Concentrations
PVC	Poly vinyl chloride
RCR	Risk Characterisation Ratios
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SCCPs	Short-chained chlorinated paraffins

STOT SE	Specific target organ toxicity - single exposure
t/y	Metric tonnes per year
U.S. NTP	U.S. National Toxicology Program
UK	United Kingdom
UVCB	Substance of Unknown or Variable Composition, Complex reaction products or Biological materials
VPE	Vinylethoxysiloxane-propylethoxysiloxane copolymer
WEEE	Waste Electrical and Electronic Equipment

CONTEXT and SCOPE of the substance assessment

The substance assessment of medium chain chlorinated paraffins (MCCPs) – Alkanes, C14-17, chloro[1] is being performed as part of the "*Study on the review of the list of restricted substances and to assess a new exemption request under RoHS 2 – Pack 15*". With contract No. 07.0201/ 2017/772070/ENV.B.3 implementing Framework Contract No. ENV.A.2/FRA/2015/0008, a consortium led by Oeko-Institut for Applied Ecology has been assigned by DG Environment of the European Commission to provide technical and scientific support for the review of the list of restricted substances and to assess a new exemption request under RoHS 2. This study includes an assessment of seven substances / group of substances[2] with a view to the review and amendment of the RoHS Annex II list of restricted substances. The seven substances have been pre-determined by the Commission for this task. The detailed assessment is being carried out for each of the seven substances in line with a uniform methodology which was developed as a part of this study[3].

In the course of the substance assessment, the 1st stakeholder consultation was held from 20 April 2018 to 15 June 2018 to collect information and data for the seven substances under assessment. Information on this consultation can be found at Oeko-Institut's project webpage at: http://rohs.exemptions.oeko.info/index.php?id=289.

For MCCPs, a total of eight contributions were submitted by different stakeholders. An overview of the contributions submitted during this consultation is provided in Appendix I. The contributions can be viewed at http://rohs.exemptions.oeko.info/index.php?id=293.

In the course of the 1st stakeholder consultation, a dossier on MCCPs was submitted by the Swedish Chemicals Agency KEMI proposing to add Medium-Chained Chlorinated Paraffins to the list of restricted substances.[4] This document was submitted to the Commission in June 2018 as the first restriction proposal by a Member State.[5] The proposal follows the (former) RoHS Dossier template (see footnote 3) and serves as an essential foundation for the dossier at hand, whereby additional and new information from stakeholders including a position paper submitted by the industry association EuroChlor[6] have been taken into account.

The current dossier has been prepared based on publicly available information and stakeholder input, and is now presented to the 2nd stakeholder consultation. The aim of the 2nd consultation is to receive further information, data and comments:

---

1 Hereafter „MCCPs"

2 For the sake of better readability hereafter the term substance will be used for single substances as well as for group of substances.

3 This methodology includes a dossier template for substance assessment which had been prepared by the Austrian Umweltbundesamt GmbH in the course of a previous study. The methodology for substance assessment has been revised based on various proposals from and discussions with stakeholders. Among others, revisions have been made to clarify when the Article 6(1) criteria are considered to be fulfilled and how the precautionary principle is to be applied. The methodology has also been updated in relation to coherence to REACH and other legislation and publicly available sources of relevance for the collection of information on substances that have been updated and added. The methodology is available at https://rohs.exemptions.oeko.info/index.php?id=341

4 Swedish Chemicals Agency KEMI (2018): ROHS Annex II Dossier MCCP, Proposal for a restriction of a substance in electrical and electronic equipment under RoHS; https://www.kemi.se/global/rapporter/2018/report-4-18-rohs-annex-ii-dossier-mccp.pdf, last viewed 24.07.2018

5 European Commission Environment DG at http://ec.europa.eu/environment/waste/rohs_eee/substances_en.htm, last viewed 24.07.2018.

6 EuroChlor (2018): Euro Chlor views on the proposal to add medium-chain chlorinated paraffins (MCCP) to Annex II of the Restriction of Hazardous Substances Directive (RoHS); Position Paper, July 2018.

- To consolidate the data compiled in the dossier and pinpoint prevailing data gaps;
- To verify assumptions that were taken in absence of specific data for estimations on applications and exposure aspects;
- To gather sector-specific data where it is not possible to make a relevant distinction on the use of the substance in various EEE sectors on the basis of currently available information;
- Correct interpretation of information and comments provided during the first consultation.

After the revision of the dossiers and their completion, a final stakeholder meeting shall be held to allow stakeholders to comment on conclusions and recommendations arrived at in the dossier.

1. IDENTIFICATION, CLASSIFICATION AND LABELLING, LEGAL STATUS AND USE RESTRICTIONS

1.1 Identification and physico-chemical properties of the substance

Medium-chained chlorinated paraffins (MCCPs), also known as chloro-paraffin, refer to a group of substances rather than a single one. Commercially available MCCP products generally consist of a mixture of linear chloro-alkanes with a medium carbon chain length in the range of C14-17, (EC No: 287-477-0, CAS No: 85535-85-9). Technical-grade MCCPs for industrial applications contain a broad range of combinations of carbon chain length and degree of chlorination between *20-70 % by weight*.[7] The chlorination levels of commoditised products are usually in the range of 40-70 % by weight mass as shown in Table 1-1 (EU RAR 2005).[8] Under the REACH and CLP regulations, MCCPs are classified as substances from the UVCB category (Unknown or Variable Composition, Complex Reaction Products or Biological Materials).

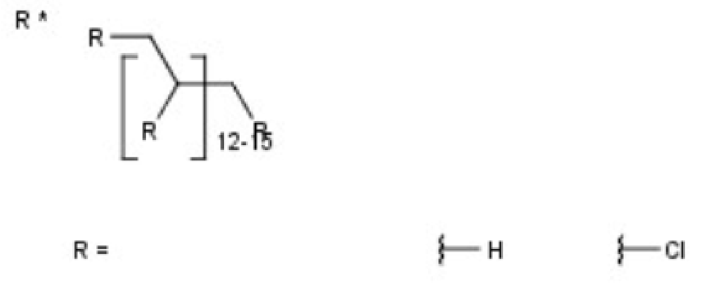
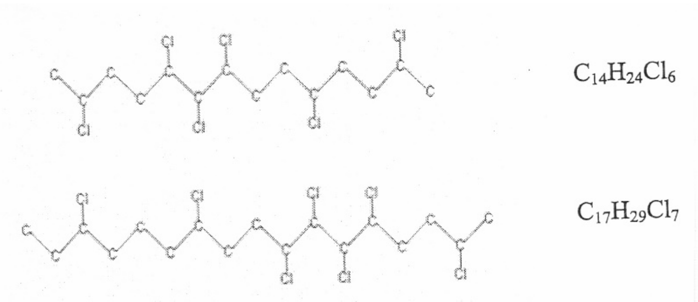
1.1.1. Name, other identifiers, and composition of the substance

Table 1-1: Substance identity and composition of medium-chained chlorinated paraffins (MCCPs)

Chemical name	Medium-chained chlorinated paraffins (MCCPs)
EC number	287-477-0
CAS number	85535-85-9
IUPAC name	Alkanes, C14-17, chloro
Index number in Annex VI of the CLP Regulation	602-095-00-X
Molecular formula	The substance group includes a range of chlorinated isomers of C14 to C17 paraffin. CxH(2x-y+2)Cly, where x = 14-17 and y=1-17
Molecular weight (range)	233 - 827 g/mole
Synonyms	Chlorinated paraffin (C14-17); chloroalkanes, C14-17; chloroparaffin; chloroparaffine, C14-17; medium-chained chlorinated paraffins
Structural formula	ECHA provides the following general chemical formula:

7 European Union Risk Assessment Report EU RAR (2008): Alkanes, C14-17, chloro (MCCP) - Part II Human Health, European Commission, Joint Research Centre, Institute for Health and Consumer Protection ; http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/15069/1/lbna24589enn.pdf, last viewed 24.07.2018

8 European Union Risk Assessment Report EU RAR (2005): Alkanes, C14-17, chloro (MCCP) - Part I - environment, Luxembourg: European Commission; https://echa.europa.eu/documents/10162/ad6eebf1-49b2-4a7b-9f73-a2c11109ff0c, last viewed 24.07.2018

	 Structure of two MCCP compounds according: 
Degree of purity	≥99 % (technical grade MCCPs traded in the EU)
Remarks	UVCB substance Commoditised MCCPs traded in the EU contain less than 1 % of LCCPs (long-chain) or SCCPs (short-chain) whereas commoditised MCCPs available in other world regions (e.g. China) may contain higher concentrations of SCCP/LCCPs

Sources: (ECHA, 2018; EU RAR, 2005; KEMI, 2018)

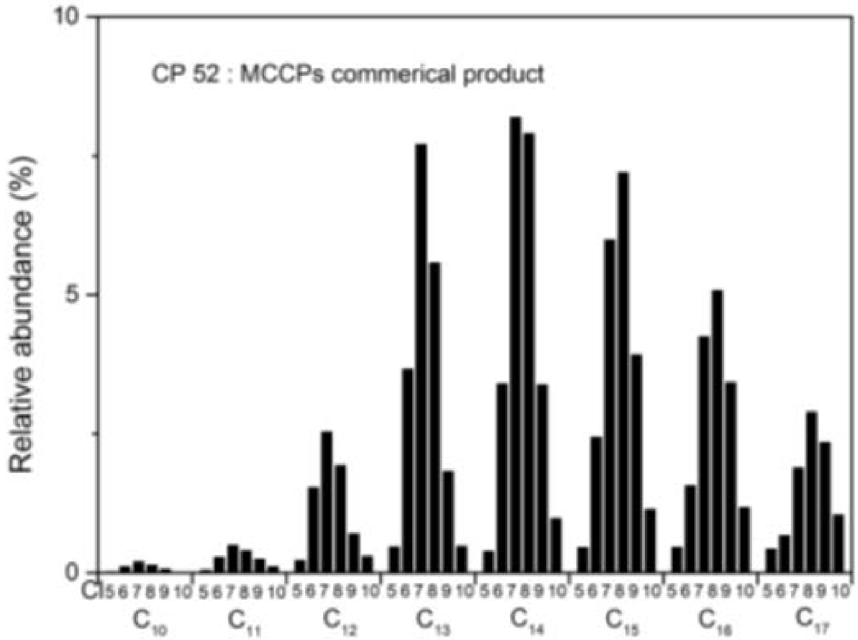
Commercial MCCPs consist of a mixture of isomers, where the unwanted content of short- or long-chained paraffin congeners depends on the purity of the paraffin feedstock used in production. According to KEMI (2018), MCCPs traded in the EU are thought to contain less than 1 % of short- or long-chained congeners, which is a result of the manufacturers' dedicated quality policies. However, the categorisation of MCCPs by CAS number is not consistent with the product specifications in markets outside the EU. Commercial products such as "CP-52", which is traded in China under the label of MCCP and which accounts for 80 % of the market volume, are marketed with regard to their chlorination level rather than the carbon chain length of their constituents.

Technical-grade chlorinated paraffins such as CP-52 have been shown to contain higher amounts of short-chained congeners (KEMI, 2018). Figure 1-1 shows the analytically derived congener profile of carbon and chlorine found in various samples of CP-52 (Yin 2016)[9]. The results suggest that commercial products labelled as CP-52 contain varying amounts of chained paraffin congeners with chain lengths outside the range of C14 to C17 that are attributed to the CAS number of MCCPs. For instance, sample "7" contains 2.5 % C12 and 7.5 % C13 paraffins, which are allotted to the group of short-chained chlorinated paraffins (SCCPs).

To this end, EuroChlor (2018) remarks "*it would be incorrect to assume that any <C14 chlorinated alkanes found in such imported products are SCCPs, as defined by the above CAS and EINECS numbers*".

9 https://pdfs.semanticscholar.org/41b2/847fe723787a863568f1376aa840042fc8b6.pdf (accessed on 11.11.2019)

Figure 1-1: Congener profile of carbon and chlorine in technical chlorinated paraffins traded on the Chinese market under the name "CP-52"



Source: (Yin 2016)[10]

EuroChlor (2018) explains the occurrence of short-chained parrafins in technical MCCPs as follows: The classification of chloro paraffins in form of UVCB substances that are identifiable by CAS and EINECS numbers originates from market practices in the past. The distinction between SCCPs, MCCPs and LCCPs was introduced in the early 1980s to describe mixtures of chloro paraffins with similar properties. Thus, the "grouping" of these substances was motivated by technical considerations rather than their respective hazard profiles. The assignment of hazards profiles to these different UVCBs is considered to be misleading as the substance "groups" have not been defined for the purpose of applying regulatory restrictions based on their individual hazard profiles.

Referring to the arbitrary distinction between SCCPs and MCCPs, EuroChlor (2018) further argues that each substance group is likely to contain congeners that are assigned to the other group. These constituents are not considered as impurities. For instance, the MCCP group (C14-17) contains paraffins with C13 or C18 carbon chain length, which are assigned to the SCCP or LCCP groups. However, since the groups were not defined for the purpose of hazard classification, it is considered pointless to treat these congeners as impurities of the MCCP group in the context of regulatory risk assessments.

Against this background it is important to note that a large portion of EEE products placed on the European market is imported from China. Those products may contain a mixture of chlorinated paraffins that do not match with the classification of MCCPs in the EU. EEE products containing

[10] https://pdfs.semanticscholar.org/41b2/847fe723787a863568f1376aa840042fc8b6.pdf (accessed on 11.11.2019)

commercial MCCPs such as CP-52 may contain certain amounts of chloro paraffins that are beyond the scope of this substance evaluation dossier on MCCPs with CAS number 85535-85-9.

1.1.2. Physico-chemical properties

Table 1-2 summarises the physico-chemical properties of MCCPs as compiled by KEMI (2018). It has to be born in mind that the physico-chemical properties of this substance group *cannot be described as one "true value but rather a range of values." Glüge et al. (2018).*[11] In other words, the properties of a commercial MCCP product may differ depending on its chain length and chlorination degree.

Table 1-2: Overview of physico-chemical properties of MCCPs

Property	Chlorine content (% wt)	Value	Remarks
Physical state at 20°C and 101.3 kPa	40-63	Liquid	
Melting / freezing point	Not specified (up to 63 %)	-50 to 25 °C	Commercial MCCP mixtures do not have a specific melting point, but they gradually soften when heated over a certain range of temperature levels.
Boiling point	Not specified	>200 °C	Decomposition with release of HCl
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	
Water solubility	51	0.005-0.027 mg/L at 20 °C	Water solubility varies with both carbon chain length and degree of chlorination (EU RAR 2008)
Partition coefficient n-octanol / water (log POW)	45	5.52-8.21 Log P_{ow}	
	52	5.47-8.01 Log P_{ow}	
Density	41	1.095 g/cm3 at 20 °C	Density increases with increasing degree of chlorination.
	56	1.315 g/cm3 at 20 °C	
	40-58	1.1-1.4 g/cm3 at 25 °C	
	56	1.28-1.31 g/cm3 at 60 °C	

Source: KEMI (2018)

[11] Glüge, J., Schinkel, L., Hungerbühler, K., Cariou, R., Bogdal, C. (2018): Environmental risks of medium-chain chlorinated paraffins (MCCPs) - A review. Environ. Sci. Technol. (52):12, pp 6743-6760

1.2. Classification and labelling status

Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging (CLP)[12] provides for a unified means of communicating the hazards presented by chemicals to workers through classification and labelling. Annex VI of the Regulation lists substances where a harmonised classification exists based on e.g. human health concerns. That substance list is regularly adapted by engagement of Member State Competent Authorities and ECHA.[13]

For an explanation on the human and environmental hazards, see sections 3 and 0.

Classification in Annex VI of Regulation No 1272/2008 (CLP)

Table 1-3: Classification according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No.	International Chemical ID	EC No.	CAS No.	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
602-095-00-X	alkanes, C14-17, chloro; chlorinated paraffins, C14-17	287-477-0	85535-85-9	Lact. Aquatic Acute 1 Aquatic Chronic 1	H362 H400 H410	GHS09 Wng	H362 H410	EUH066		

Source: Annex VI Regulation No 1272/2008; https://echa.europa.eu/de/information-on-chemicals/annex-vi-to-clp, last viewed 19.04.2018

In summary, the CLP classification for MCCPs flags the following hazards:

- Reproductive toxicity on or via lactation of breast-fed children (H362), and
- Very high acute and chronic toxicity to aquatic life (H400).

Self-classification(s)

Manufacturers, importers or downstream users have to apply a harmonised classification if available, and have also the possibility to (self)classify and label hazardous substances and mixtures containing such substances. Self-classification can indicate an additional hazard, for example, which, so far has not been adequately reflected by the harmonised classification. The following provides an overview of additional hazards based on self-classifications.

The ECHA database's Classification and Labelling Inventory contains information on notified and registered substances received from manufacturers and importers. With regard to MCCPs, as of November 2019, there are a total number of 378 companies notifying self-classification (so-called notifiers).[14] Most notifiers follow the harmonised classification (332 of 378 notifications: ~ 88 %). So

[12] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH).

[13] For further information, see https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling, last viewed 19.04.2018

[14] ECHA CL Inventory: Entry for Alkanes, C14-17, chloro (2019); https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/94445, last viewed 11.11.2019

far, not a single case is known where a more severe classification was notified. A minority (46 notifiers) differs from the harmonised classification by e.g. notifying only the classification of chronic aquatic toxicity or by not classifying acute aquatic toxicity (~ 6 %) at all. Thereof, 19 notifiers (5 %) provided a completely different classification by notifying skin irritation (H315 – causes skin irritation), eye irritation (H319 – causes serious eye irritation) and specific target organ toxicity by single exposure (STOT SE 3; H335 – may cause respiratory irritation); 3 notifiers (< 1 %) do not provide any classification at all.

Against this background, it can be concluded that for MCCPs, the currently available self-classifications do not indicate an additional hazard that is not reflected by the harmonised classification.

1.3. Legal status and use restrictions

1.3.1. Regulation of the substance under REACH

Since they are suspected of being PBT substances, MCCPs are on the Community Rolling Action Plan (CoRAP). They are also subject of concern regarding (environmental) exposure due to their wide dispersive use and high aggregated tonnage.[15] The UK evaluated MCCPs and acquired details on the exact composition of different MCCP products so as to verify the PBT status of different formulations. In 2014, the ECHA decided that further information on the relevant compositions of different commercial MCCP types is required.[16] The information request, to be delivered until September 2018, addresses:

- Amounts of carbon chain lengths shorter than C14 that are present at or above 0.1 % weight by weight (hereinafter 'w/w') for all of the MCCP product types supplied by the registrants.
- Aqueous and dietary exposure tests from the registrant manufacturers specifically for the test substances C14 chlorinated n-alkane with a chlorine content of 50−52 % and of 55−60 % by weight.
- Aerobic and anaerobic transformation in aquatic sediment systems for the test substances C14 chlorinated n-alkane with a chlorine content of 50−52 % and of 55−60 % by weight. And for C15 chlorinated n-alkane with a chlorine content of around 51 % by weight.
- A PBT assessment for all relevant constituents of the substance and any transformation product found to be formed in a relevant environmental compartment at any time point, at a concentration exceeding or equal to 0.1 % w/w (grouped as appropriate).

As of October 2019, the requested information has not been published yet. The status indicated by the ECHA webpage displays that the information was requested. It is thus concluded that the evaluation process of MCCPs, which was meanwhile handed over to the Swedish Chemicals Agency, is still in progress.[17]

[15] http://www.echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table?search_criteria=85535-85-9, last viewed 15.10.2019

[16] ECHA (2014): Decision on Substance Evaluation Pursuant to Article 46(1) of Regulation (EC) No 1907/2006 for alkanes , C14-17, chloro (MCCP, medium-chain chlorinated paraffins); CAS No 85535-85-9 (EC No 287-477-0); case no. A-004-2014; https://echa.europa.eu/about-us/who-we-are/board-of-appeal/decisions, last viewed 19.04.2018

[17] http://www.echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table?search_criteria=85535-85-9, last viewed 15.10.2019

The "Brief report from the 22nd PBT EG meeting (Helsinki, 3-4 September 2019)" however, points out the following conclusion:[18] *"MCCP (Medium chain chlorinated paraffins / alkanes, C14-17, chloro). This case is close to finalisation. In discussion, the general view was that a vPvB conclusion could be made for MCCP at or above 50 % chlorine by weight, but the assessment needs some refinements before finalisation."*

1.3.2. Other legislative measures

While other EU legislation does not explicitly restrict the use of MCCPs, some risk management obligations are assigned:

- Pregnant workers (Directive 92/85/EEC): As MCCPs are classified as having hazardous effects via lactation, employers should conduct risk assessments for any pregnant or breastfeeding workers and decide on the measures to be taken.
- Via its classification, MCCPs is covered by:
  - EU Ecolabel Regulation 66/2010 that stipulates that the EU Ecolabel cannot 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, according to which substances classified as Aquatic Acute 1 and Aquatic Chronic 1 have to follow requirements for holding at least 100 t (lower tier) or 200 t (upper tier).
- The Basel Convention applies to MCCPs because it includes a waste category for organo-halogen compounds in general.
- The Helsinki Convention on the Protection of the Marine Environment of the Baltic Sea Area (HELCOM) considered MCCPs as a substance of specific concern to the Baltic Sea, according to the final report of the HAZARDOUS project in 2009.[19]
- Commercial grade MCCPs may also contain Short Chain Chlorinated Paraffins (SCCPs, carbon chain lengths between 10 and 13) that are recognised as POPs and are restricted by the Stockholm Convention since 2017.

1.3.3. Non-governmental initiatives

The International Chemical Secretariat (Chemsec) specifies and updates the SIN List, which identifies potential substances of concern. The list is a measure for putting pressure on legislators to assess and, where relevant, address substances identified therein in the future in respect of relevant chemical legislation.[20] There are a number of reasons why substances are added to the SIN List, including carcinogenic properties, DNA-altering or -reproductive systems damage (CMR properties) and substances that do not easily break down and accumulate in the food chain (PBT / vPvB substances) or substances that give rise to an equivalent level of concern in terms of

[18] https://echa.europa.eu/documents/10162/21877836/Brief_report_PBTEG22.pdf/647a3dc4-6bcc-e2b7-5d29-c4b0945a0d37, last viewed 20.11.2019

[19] Helsinki Commission, Baltic Marine Environment Protection Commission (2009): Hazardous substances of specific concern to the Baltic Sea, Final report of the HAZARDOUS project; Baltic Sea Environment Proceedings No. 119; http://www.helcom.fi/Lists/Publications/BSEP119.pdf, last viewed 24.07.2018

[20] http://chemsec.org/business-tool/sin-list/about-the-sin-list/, last viewed 24.07.2018

potential damage to health and environment (such as substances with endocrine disrupting properties).

ChemSec's SIN List does not mention MCCPs as such, but refers to longer-chained "Paraffin waxes and Hydrocarbon waxes, chloro" (EC No: 264-150-0, CAS No: 63449-39-8), based on their PBT and/or endocrine disruptor properties.[21] Additionally, the SIN List also includes SCCPs due to their PBT properties.[22]

[21] http://sinlist.chemsec.org/search/search?query=SCCP, last viewed 24.07.2018

[22] http://sinlist.chemsec.org/search/search?query=63449-39-8, last viewed 24.07.2018

2. USE IN ELECTRICAL AND ELECTRONIC EQUIPMENT

2.1. Function of the substance

The main function of MCCPs is that of a **secondary plasticiser** (extender) in PVC. While *a primary* plasticiser (mainly phthalates but also phosphate esters) can be used alone, its effectiveness is enhanced if combined with a secondary plasticiser. MCCPs are thus improving the functional performance and are also significantly cheaper than primary plasticisers. In fact, the low price seems to be one of the main reasons that they are used in a wide variety of PVC applications, including cables, according to KEMI (2018). It is understood that the use of MCCPs as secondary plasticiser or extender lowers the amount of (the more expensive) primary plasticisers needed.

Moreover, MCCPs with higher chlorination levels *(i.e. >50 % wt. Cl)* provide flame retardant properties that are harnessed on top of its function as a plasticiser extender. MCCPs are used as such in PVC, rubber and other polymers, including polyurethane, polysulphide, acrylic and butyl sealants and adhesives.

It should be noted that MCCPs are currently in use as a substitute for short-chain chlorinated paraffins (SCCPs) in applications such as PVC, rubber and other plastics, paints and coatings, sealants and adhesives. The Persistent Organic Pollutants Review Committee (POPRC) noted that MCCPs are listed as *"Potential Alternatives to SCCPs in Polyvinyl Chloride Processing"*:[23] Hence, the – previously assumed - lower hazard potential in comparison to SCCPs, which are however currently under scrutiny, has so far constituted one of the functions of MCCPs in technical applications.

2.2. Types of applications / types of materials

MCCPs are used in electrical and electronic equipment (EEE) mostly as constituents of PVC insulations for electric cables and wires and other soft plastic or rubber components, including polyurethane, polysulphide, acrylic and butyl sealants.

In the following, the typical chlorine content of the MCCPs is mentioned (if available) for the respective uses. This is done against the background that MCCP compounds with a higher degree of chlorination (chlorine content of 50−52 % by weight and of 55−60 % by weight) are under REACH scrutiny for PBT properties (for further details, see section 1.3.1).

2.2.1. Cable and wire sheathing and insulation

MCCPs are used as secondary plasticisers in flexible PVC that functions as sheathing and insulation jackets for cables and wires with rated voltage of less than 250 Volt (KEMI, 2018).

The majority of secondary plasticisers used in PVC applications are medium-chain chlorinated paraffins with chlorine contents around 45 % by weight or 50-52 % by weight, with only very small amounts (<1% of total sales) of medium-chain chlorinated paraffins with higher (e.g. 56-58 % by weight) or lower (e.g. ~40 % by weight) chlorine contents (EU RAR, 2005).

[23] http://chm.pops.int/Implementation/Alternatives/AlternativestoPOPs/ChemicalslistedinAnnexA/Shortchainchlorinatedparaffins(SCCPs)/tabid/5986/Default.aspx, last viewed 24.07.2018

For cable sheathing and insulation, MCCPs with chlorination degrees of typically around 50-52% wt. Cl are preferably used as they are more compatible with PVC and have a lower volatility than lower chlorinated analogues (EU RAR, 2008). The degree of chlorination and the preferred carbon chain length also depends on which primary plasticiser is used in PVC applications and which product function is required. Increasing chlorination increases the compatibility of chlorinated paraffins with PVC and the primary plasticiser. That way, the potential for migration is reduced, but at the cost of lower mechanical flexibility of the final product.

According to KEMI (2018), MCCPs are typically added to PVC at 10-15 % w/w of the total plastic, but can reach up to 20 % of the polymer compound for sheathing or insulation of electric cables. In contrast, the MCCPs concentration in rubbers is comparatively low and does not exceed 3.8 %.

The application of PVC containing MCCPs for flexible cables insulation is predominant. This means that many EEE used in EU households may contain MCCPs. Taking into account that cables are used in more or less any kind of electrical and electronic equipment, MCCPs could be expected in any category of WEEE as well. Given its low volatility, it can be inferred that WEEE items contain almost the same concentration of MCCPs as new products.

2.2.2. Coatings, adhesives and sealants

The application of MCCPs in coatings, sealants, and adhesives is far less common than in PVC wire sheathing and insulation. MCCPs may be applied in certain polysulphide, acrylic and butyl sealants and adhesives, but the actual applications are not as frequent or as uniform as compared to the use in PVC. KEMI (2018) notes that *"it is difficult to obtain information on their market share"* for MCCP-containing sealants and adhesives in cable sheaths. While MCCPs may be applied in polyurethanes, the actual occurrence of that material in EEE could not be established.

MCCPs used in sealants as plasticisers with flame retardant properties generally have a chlorine content of 50–58 % wt. Cl. As for coatings, paints and varnishes, the actual use of MCCPs on/in EEE products hinges around *a chlorine content of 50–60 % as part of certain paints, varnishes and other coatings* (KEMI, 2018). *Resin-based, rubber or copolymer paints in EEE may also contain MCCPs as a plasticiser but "it is difficult to estimate how frequently these paints and varnishes are applied to EEE" (ibid).*

Questions for stakeholders participating in the stakeholder consultation:

1. *Please provide data on typical formulations for MCCPs as a secondary plasticiser or plasticiser (extender) in PVC in relation to the share of plasticisers and in relation to PVC mouldings in total, e.g. for cable and wire sheathing and insulation.*
2. *To what extent does the content of MCCPs vary in PVC and to what extent do requirements on flame retardancy determine the use of MCCPs and the amount used?*

2.3. Quantities of the substance used

According to KEMI (2018), the most recent estimation from industry on the quantities of MCCPs used in EEE applications originates from INEOS Vinyl, one of the major MCCP manufacturers in the EU. Data were submitted as a stakeholder contribution during a consultation under RoHS, held in 2014.[24] 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. Information provided by stakeholders in the course of the present dossier preparation did not yield concrete data on more recent quantities:

- Europacable indicated *"quantities in the range of 1,000 to 10,000 t per year for the cable applications"* in the EU,[25] further explaining this to be *"a very approximate estimation, as it is not possible, for competition law reasons, to collect quantities of substances used at Europacable level. Any quantitative information on manufacturers' purchase of raw materials is considered confidential."*[26]
- EuroChlor (2018) stated on amounts that *"data on production levels cannot be legally provided due to the small size of the market here. This is restricted by EU competition law on the provision of production data."*

The quantities of MCCPs as specified in the past were summarised by KEMI (2018) as follows:

Figure 2-1: Estimations on MCCP quantities

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[20]	10,000-100,000	Unknown	2009
INEOS Vinyl's comments on Öko-Institut study (2014)	40,000	15,000	2013

Source: KEMI (2018)

Comparing the data of the EU RAR (2008) and the amounts provided by INEOS ChlorVinyls (2014), the conclusion could be drawn that the total market volume of MCCPs in the EU decreases: In 2006, approximately 64,000 tonnes of MCCPs were used in total in the EU 25 and around 34,676 tonnes thereof were used in PVC. In 2014, the total amount of MCCPs was indicated at about 40,000 tonnes. The MCCP amount used for PVC cable formulations was estimated to account for about 15,000 tonnes. The general trend towards a declining consumption of MCCPs in the EU can be explained in part by the declining use of PVC compounds in European cable manufacturing industry. On the other hand, the amount of MCCP contained in finished EEE that are imported into the EU 28 is assumed to increase. KEMI (2017)[27] suggests that significant

24 INEOS ChlorVinyls (2014): Contribution submitted 24.03.2014 during stakeholder consultation; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140324_INEOS_Contribution_RoHS_SC_Substance_Review_MCCP.pdf, last viewed 19.04.2018

25 EuropaCable (2018a): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_EUROPA_CABLE_MCCP_consultation_1_20180615.pdf, last viewed 24.07.2018

26 EuropaCable (2018b): Information provided to Questionnaire for Clarification, submitted 09.07.2018

27 Swedish Chemicals Agency KEMI (2017): Study of a possible restriction of MCCP in electrical and electronic equipment regulated under RoHS, PM 2/17, May 2017; https://www.kemi.se/global/pm/2017/pm-2-17-study-of-a-possible-restriction-of-mccp-in-electrical-and-electronic-equipment-regulated-under-rohs.pdf, last viewed 19.04.2018

volumes of MCCPs enter the EU as part of cable insulation that is incorporated in imported EEE goods.

KEMI (2018) assumes that imports and exports of MCCPs in PVC and/or EEE are largely equivalent. Many of the imported semi-finished products that contain MCCPs are thought to be re-exported, notably in form of industrial EEE. Although data are insufficient to specify mass flows in detail, the 2017 assessment estimated the amount of 15,000 tonnes per year for calculating emissions. This amount is presumably an underestimation, because *"according to Eurostat the import is 2.6 times bigger than the export for certain groups of EEE."* (ibid)

As for the import of MCCPs as part of finished EEE goods, Glüge et al (2018)[28] point to the fact that manufacturers in Asia indicate the content of chlorinated paraffins in products in regard to the chlorine content rather than specifying the MCCPs according to the carbon chain length or CAS numbers. In an attempt to estimate the amounts of chlorinated paraffins contained in EEE that is imported in the EU from China, Glüge et al. (2018) refer to the latest available production figure from China are from 2013 and indicate an amount of 1,050,000 tons; the International Chlorinated Alkanes Industry Association (ICAIA) stated that nearly 90 % of the chlorinated paraffins produced in China in 2012 were CP-52 (with a chlorine content of 52 %). Glüge et al. (2018) estimates conservatively that "*MCCPs might have been produced in the order of 600 000 t in China in 2013. This number is much larger than any of the production amounts reported in literature for North America, Russia, or the EU and indicates that.*"

Questions for stakeholders participating in the stakeholder consultation:

3. *Please provide evidence for the above-cited assumption that imports and exports of MCCPs in PVC and/or EEE are largely equivalent.*
4. *Are there different assumptions on use of MCCPs in articles, which take into account the different levels of the supply chain, especially electronic components (including cables and encapsulated components), electronic assemblies, and electronic equipment?*

[28] Glüge, J., Schinkel, L. et al (2018): Environmental risks of medium-chain chlorinated paraffins (MCCPs) - A review. Environ. Sci. Technol. (52):12, pp 6743-6760

2.4. Potential impacts of the substance on the environment and on health during the use of EEE

Potential impacts from MCCPs during the use of EEE can arise by a release of MCCP compounds from finished EEE products containing PVC and soft PVC cable insulation in households. Such a release may occur in form of migration and affects volatile compounds rather than non-volatile substances. Higher degrees of chlorination (typically around 50-52 % wt. Cl), which are often found in PVC, result in lower volatility (EU RAR, 2008). This is one of the reasons why MCCPs has so far been considered a less hazardous substitute for SCCPs. Section 6 discusses monitoring results for indoor air and indoor dust samples.

3. HUMAN HEALTH HAZARD PROFILE

The hazard characterisation of UVCB substances is generally challenging and this is true for MCCPs in particular, since the group encompasses a plethora of distinct heterogeneous substances. MCCPs are characterised by molecules of four chain lengths (C14-17) and variable chlorination percentages. KEMI (2018) states, that *"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."*

3.1. Critical endpoint

There is some evidence in the available literature that MCCPs are **not acutely toxic** for humans. As for **repeated dose toxicity**, kidney effects ('chronic nephritis' and tubular pigmentation) were reported as well as effects on the liver and thyroid after dietary exposure. Repeated dermal exposure may cause defatting to a certain degree. Repeated dose toxicity has a NOAEL of 23 mg/kg/day, based upon effects seen in rat kidney. Exposure to a MCCP (40 % chlorination) has been shown to lead to thyroid effects (follicular cell hypertrophy and hyperplasia). The thyroid effects were concluded to be secondary to changes in liver enzyme activity and of no real significance for humans (KEMI 2018).

As for skin and eye **irritation and sensitisation** potentials, MCCPs seem to be **rather non-problematic.** Human skin exposure to C15 chlorinated paraffin for 24 hours leads to a dermal absorption value of 1 % (KEMI 2018). Nevertheless, concerns regarding **unknown long-term effects** remain, for example the tendency of strongly lipophilic substances like MCCPs to enter breast milk.

As **for reproductive and developmental effect**s, 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, KEMI 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 relationship at higher exposure levels. MCCPs were proposed for endocrine disruption according to the Endocrine Disruptors Database[29] in 2007.

As for **mutagenicity and carcinogenicity,** MCCPs (C14-17 of 40–52% chlorination) were not found to be mutagenic. None of the usually applied test methods such as the Ames test,[30] gene mutation assays or in-vivo bone marrow tests, have provided any evidence on elevated risk levels. Epidemiological data on carcinogenicity from exposed human populations or toxicology studies are not available.

However, (KEMI 2018) deems it reasonable to infer a similar carcinogenic potential of MCCPs to that of SCCPs, at least in qualitative terms.

The study argues that the similarities between MCCPs and SCCPs in physicochemical properties in relation to other toxicological endpoints (particularly the effects on liver, thyroid and kidneys on

29 http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#report3: MCCPs are assigned endocrine disruption Cat. 1. This implies that at least one in-vivo study provides clear evidence for endocrine disruption in an intact organism

30 The Ames test uses bacteria to test whether a given chemical can cause mutations in the DNA of the test organism.

repeated exposure) suggest at least the possibility of similarities to SCCPs. C12 chlorinated paraffins (60 % chlorine by weight) are listed by the International Agency for Research on Cancer (IARC) as “Possible Carcinogens” and in the U.S. National Toxicology Program (NTP) carcinogen list as “reasonably anticipated to be a carcinogen”.

Therefore, KEMI (2018) reasons that *“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.”* Although the available evidence does not seem to suggest that MCCPs pose a relevant mutagenicity and carcinogenicity risk to humans, the EU RAR invokes the precautionary principle when proposing a NOAEL of 23 mg/kg/day for repeated dose effects on the kidney as a carcinogenicity endpoint (JRC-IHCP, 2011).

Toxicokinetics: Chlorinated paraffins are widely distributed throughout the liver, kidney, intestine, bone marrow, adipose tissue and ovary. Whilst the metabolic pathways are uncertain, MCCPs may be excreted via the renal, biliary and pulmonary routes (as CO2). In addition, lactation in nursing mothers (IPCS, 1996) could be a pathway of elimination (KEMI, 2018).

3.2. Existing Guidance values (DNELs, OELs)

Derived No Effect Levels (DNEL) for MCCPs are shown in Table 3-1; they have been extracted from the publicly available ECHA databases, which are based on information from the REACH registration dossiers. It should be stressed that information provided by registrants has not been subject to scrutiny by ECHA or any EU expert group. In comparison to these, the DNELs compiled by the UK Chemicals Agency in the Annex XV report (2008) are included.

It should be noted that the pending evaluation of MCCPs as a potential PBT substance would result in a repeal of these DNELs.

Table 3-1: Guidance DNEL values for worker DNEL systemic effects

Population	Local / systemic effect	Effects	DNEL*	UK (2008): Annex XV Restriction Report*
Workers	Inhalation Exposure	Systemic effects Long term	6.7 mg/m^3	1.6 mg/m^3 Inhalation route for kidney effects/carcino-genicity
	Dermal Exposure	Systemic effects Long term	47.9 mg/kg bw/day	11.5 mg/kg bw/day
	Eye Exposure	-	Low hazard No threshold derived	
General Population	Inhalation Exposure	Systemic effects Long term	2 mg/m^3	
	Dermal Exposure	Systemic effects Long term	28.75 mg/kg bw/day	
	Oral Exposure	Systemic Effect Long term	580 µg/kg bw/day	
	Eye Exposure	-	Low hazard No threshold derived	

Source: UK chemicals agency (2008) cited in KEMI (2018) * bw=body weight

4. ENVIRONMENTAL HAZARD PROFILE

MCCPs are UVCBs and the properties depend on the chain length and the chlorination degree of the numerous possible congeners.

Glüge et al. (2018) point out that MCCP congeners with more than 46 % chlorine have to be considered as persistent in the environment as results from biodegradation tests in secondary activated sludge suggest.

4.1. Potential for secondary poisoning and bioaccumulation

The bioaccumulation potential of MCCPs is considered to decrease with increasing carbon chain length and chlorine content, according to Glüge et al. (2018). ECHA suspects C14 chlorinated n-alkane with a chlorine content of 50−52 % and of 55−60 % as potentially bioaccumulative and therefore requested further testing under REACH (see section 1.3.1).

Glüge et al. (2018) note that besides the requested aqueous and dietary exposure tests by ECHA from the registrant, manufacturers tests for MCCPs with other carbon chain lengths and chlorination degrees will most probably be necessary to conclude whether or not MCCPs (or single congener groups of the MCCPs) should finally be considered as bioaccumulative.

The following figure shows an overview on the estimated P and B properties of MCCP congeners adapted from ECHA's decision on Substance Evaluation for MCCPs.

Figure 4-1: Estimated P & B properties of potential constituents of MCCPs

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

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

Source: KEMI (2018)

4.2. Endpoints of concern

According to Glüge et al. (2018), MCCPs meet the toxicity threshold defined under REACH (chronic NOEC or EC10 for freshwater organisms below 10 µg/L). Therefore, they should be considered toxic to the environment. This is in line with the CLP Regulation, which classified MCCPs as acute and chronic toxic to the aquatic environment (H400 - Very toxic to aquatic life and H410 - Very toxic to aquatic life with long lasting effects).

4.3. Guidance values (PNECs)

KEMI (2018) compared the Predicted No Effect Concentrations (PNEC) for MCCPs calculated in the EU RAR where the NOECs value was determined for the registration information in the ECHA database and found that the registrants used the same starting points to derive the PNECs.

The PNEC values as compiled by KEMI (2018) are presented in the following figure.

Figure 4-2: PNEC values 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
$PNEC_{soil}$	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

Source: KEMI (2018)

Conclusions on health and environmental hazard

First, it should be noted that with respect to the environmental and human health hazards MCCPs are understood to pose a lower risk than the short-chained chlorinated paraffins. While toxic effects seem to play a role, carcinogenicity cannot either be confirmed or be excluded. There are warnings regarding human health risks in terms of their endocrine disrupting properties and possible harm via lactation (H362). MCCPs however have to be considered as highly relevant for the environment especially taken into account the pending substance evaluation for PBT properties as well as their toxicity to aquatic organisms (H400 + H410).

5. WASTE MANAGEMENT OF ELECTRICAL AND ELECTRONIC EQUIPMENT

5.1. Description of waste streams

5.1.1. Main materials where the substance is contained

MCCPs are used as secondary plasticisers in flexible plastics, rubbers and other polymers that are applied in a multitude of application areas. Out of the total MCCP consumption in the EU, 54 % is used in PVC products, 11 % in rubber and 35 % in other polymers. Out of these, EEE products represent the largest application area. KEMI (2018) assumes that within the EEE sector, 83 % of MCCPs are used in PVC and 17 % in other polymers. The following considerations focus on the fate of MCCPs in the end of life treatment of PVC insulated cable and wires that are constituents of WEEE. Other MCCP-containing plastic parts and coatings found in WEEE are not thought to undergo specific treatment in regard to their MCCP content.

5.1.2. WEEE categories containing the substance

Cables and wires meet the definition of EEE as set out in Article 3(1)(a) of the WEEE Directive 2012/19/EU. Cables that are components of another EEE (internal – permanently attached – or externally connected and removable but sold together or marketed/shipped for use with the EEE), fall within the scope of the recast WEEE Directive (coming into force in 2018). Individual cables, that are not part of another EEE, are considered as EEE themselves and hence fall within the scope of WEEE. Only non-finished cables i.e. cable reels without plugs would be out of the scope of WEEE.

PVC insulated cables and wires principally occur in almost all EEE products although highly integrated products, such as smart phones, may barley contain discrete internal wires. The following lists EEE categories (Annex III of the WEEE Directive), which are likely to contain PVC insulated cables that contain MCCPs:

- Category 1: Temperature exchange equipment (e.g. refrigerators);
- Category 2: Screens, monitors and equipment containing screens having a surface > 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 (external dimension more than 50 cm).

Lamps (category 3) are not thought to contain PVC insulated cables or wires in relevant quantities, according to KEMI (2018). However, the authors of the dossier at hand remind on the fact that LED (Light Emitting Diodes) strips, which are nowadays widely incorporated in luminaires and in other products, contains flexible insulation and electrical wiring, as demonstrated by Figure 5-1.

Figure 5-1: Flexible LED-stripe (Light Emitting Diodes) containing internal wiring and insulation based on flexible polymers

Source: Oeko-Institut

Questions for stakeholders participating in the stakeholder consultation:

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

5.2. Applied waste treatment processes

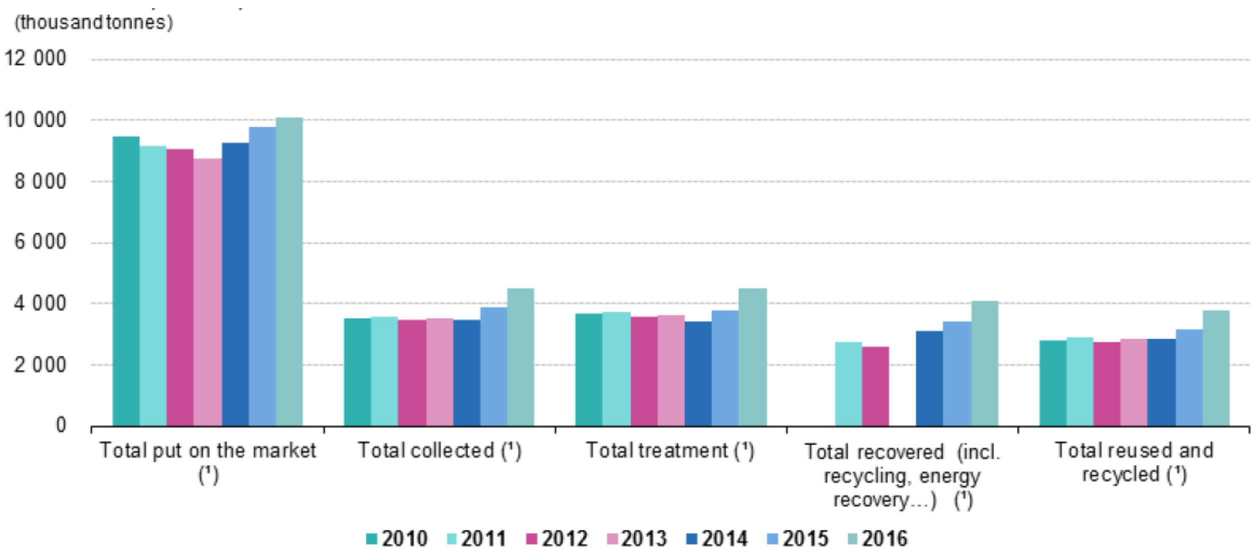
WEEE shall be collected separately from household waste, according to the collection targets specified WEEE Directive, and then recycled. In the EU, collection and recycling of WEEE, containing MCCPs, shall be implemented according to the following standards:

- EN 50625-1: Collection, logistics & treatment requirements for WEEE - Part 1: General treatment requirements
- TS 50625-5: Collection, logistics & treatment requirements for WEEE -- Part 5: Specification for the end-processing of WEEE fractions- copper and precious metals

However, collection rates of WEEE in the EU have been below 50 % (as of 2016), according to Eurostat (see Figure 5-2).[31] A collection target of 65 % applies since the beginning of 2019. This means approximately half of the generated amounts of WEEE are currently not collected and treated separately. The fate of not collected WEEE is uncertain, possibly old EEE products are incinerated together with household waste. A certain amount of end of life EEE might be exported abroad. According to the Countering WEEE Illegal Trade (CWIT) project in Europe in 2012, WEEE which is not part of the officially reported amounts of collection and recycling systems, was exported and recycled under crude conditions outside Europe. It is to be assumed that MCCPs contained in these waste flows does not undergo controlled end of life treatment.

[31] Eurostat (2019): Waste statistics -electrical and electronic equipment. https://ec.europa.eu/eurostat/statistics-explained/pdfscache/32212.pdf. last viewed: 12.11.2019

Figure 5-2: Total EEE put on the market and WEEE collected and recycled in the EU (2010-2016)



Source: Eurostat (2019)

Collected WEEE undergoes manual dismantling or mechanical shredding, typically in large metal shredders, which can be combined with automated material sorting. External cables adhering to WEEE items must be removed and this can be performed before or after the manual dismantling or mechanical shredding processes. While manually dismantled cable scrap is usually a mono-fraction, consisting of cables and connectors with undamaged plastic insulation, the shredding products are usually mixtures of granulated metals and plastics. These granules need to be separated by means of physical or gravimetric separation processes. From these sorting processes, MCCPs are likely to end up in mixed plastic enriched fractions but partly in PVC residue that remains in the copper enriched fraction.

5.2.1. Initial treatment processes applied to the WEEE containing the substance of concern

Table 5-1: Initial treatment processes applied to different categories of WEEE

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

5.2.2. Treatment processes applied to wastes derived from WEEE containing the substance of concern

Recyclables and residues separated from WEEE normally undergo further treatment processes. 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. While the metal enriched fraction is sent to copper smelters and refiners, the MCCP-relevant fractions encompass different concentrates of plastics (PVC and others) as well as electronic components, depending on the process technologies applied:

Cables:

- Transports and storage of WEEE and intermediate recycling fractions and wastes
- Shredding and automated sorting of metals and plastic insulation material
- Recycling of non-ferrous metals in copper smelting and refining plants
- Recycling of pre-sorted PVC
- Incineration of plastic-rich residues in dedicated waste incinerators
- Landfilling of incineration residues

Electronic components (additional to the above):

- Shredding and automated sorting
- Recycling of non-ferrous metals in copper smelters
- Co-incineration of non-metallic residues in copper smelters

The economic driver of cable recycling is recovery of copper. The non-metal fraction is composed of the various polymers used in cable insulations i.e. PVC, PE, HDPE, VPE and rubber, as well as metals residues. The plastics fraction is usually incinerated. Plastics recycling is of limited use today for PVC cable recycling; therefore, the focus will be on mechanical recycling. In 2015, over

100,000 tonnes of PVC cable waste were collected and in 2016, around 150,000 tonnes of PVC cable waste recycled.[32]

PVC from cable recycling that is not recoverable is usually incinerated in waste incineration plants. The combustion process bears a risk of dibenzo-p-dioxins and furans formation of from MCCP during incineration of PVC but this possibility is not further assessed. It is assumed, that municipal waste incinerator plants and metal smelters in the EU, run at sufficiently high temperatures (>900°C) so to prevent the formation/reformation of dioxins and are equipped with state of the art waste gas treatment so that emissions of these pollutants into the environment are below the allowed thresholds.

5.3. Waste treatment processes relevant for assessment under RoHS

Releases of MCCPs during WEEE treatment are to be expected above all during the **shredding of PVC cables as well as for mixed WEEE,** which takes place at a large number of installations for disposal as well as for the recycling. During shredding residues that contain polymers (mainly PVC) are likely to contain MCCPs bound to the surface of the polymers. Such residues occur as dust and swirls of material enable MCCPs also to enter into the vapour phase.

The conversion of PVC recyclate may contain **calendaring** as a process step. Although, this is no inherent waste treatment process, it is of relevance as recycling and initial conversion of recyclate may occur in the same manufacturing sites. If for the calendaring higher temperatures (> ambient temperature) are used, releases through evaporation are more likely.

The importance of the treatment processes for the assessment under RoHS will be commented on in the following sections.

The other WEEE treatment processes are considered of low relevance regarding MCCPs for different reasons: either they do not operate in a temperature range that is relevant for MCCP evaporation (above the ambient temperature but lower than the 900°C incineration temperature) or a process involves material parts that are too big to play a role for inhalation. In general, but especially for incineration and disposal, it is assumed that appropriate measures are taken and suitable to prevent releases, e.g. the appropriate construction of landfills so that leachate does not play a significant role.

5.4. Releases from (relevant) WEEE treatment processes

The figures below are generally based on the assumption of an annual MCCP consumption of 15,000 t in EEE in the EU (KEMI 2018, p34). This figure is almost certainly an underestimate as it solely takes into account the MCCPs used in manufacturing inside the EU but not the MCCP that has been imported as a constituent of final EEE goods (see section 2.3). Thus, it is very likely that more than 15,000 t/a of MCCP is contained in all EEE, including products manufactured as well as imported into the EU.

It should be noted that KEMI (2018) seemingly neglects the MCCPs contained in imported EEE. Since the amount of MCCPs co-imported in EEE goods is unknown, the estimation presented below indicates that data gap with the term “plus X”.

[32] VinylPlus, available at https://vinylplus.eu/uploads/Modules/Bannersreport/vinylplus-progress-report-2017.pdf , accessed on 30 July 2018.

There are four principal endpoints for WEEE, each having specific implications on the fate of the MCCPs contained in PVC-based cable and wire insulation materials.

- **WEEE collected separately:**

  Under the assumption that 49 % of EEE put on the market is collected as WEEE in the following years (Eurostat, 2019), this means[33] that approximately **half of the annual MCCP-inputs** to the European EEE market finally **end up in the dedicated WEEE treatment** channel.

  In terms of weight, 4.5 million tonnes of WEEE are collected per year (as of 2016) in the EU-28 (Eurostat, 2019). The quantity of MCCP in WEEE is the same as the MCCP content in EEE placed on the European market (i.e. 15,000 plus X t/a) since there is no significant release of MCCPs during the use phase of EEE. Thus, based on a 49 % collection rate, it can be estimated that the MCCP input to WEEE treatment channel is 7,350 plus X t/a (= 49 % × 15,000 plus X t/a).

  This amount enters subsequent cable recycling processes, including manual dismantling and mechanical shredding / separation processes. The MCCPs contained in the separated PVC fraction will be destroyed in the process of incineration in state-of-the-art waste incinerators (i.e. at temperatures >900°C).The highest MCCP releases are expected during shredding for recycling and mixed waste of and electronic products (WEEE) as outlined earlier in the preceded section.

  Now looking at MCCP in end-of-life EEE, another uncertainty exists. Concerning the amount of WEEE that enters separate collection and disposal routes (i.e.), this leaves 51 % of EEE that ends up in municipal waste incineration, landfilling, exports and remains unaccounted for. Another ~50 % (i.e. 7,650 plus X t/a) of MCCPs end up in one of the following three disposal routes:

- **Reused WEEE:**

  A small percentage (ca. 1 % according to Eurostat data for 2012) of WEEE may be reused.[34] The MCCPs contained therein remain in the second hand products and re-enter the WEEE at the end of the second life phase.

- **WEEE collected as municipal solid waste**:

  The amounts of WEEE entering this disposal route are uncertain. However, experiences from WEEE collection suggest that a large share of end-of-life EEE is neither turned in as WEEE nor disposed of as household waste but rather stockpiled in the consumers` households for a longer period of time. While the MCCPs contained in stockpiled end-of-life EEE remains therein until it eventually is considered WEEE and disposed of, the MCCPs will be destroyed in the process of incineration in state-of-the-art municipal waste incinerators (i.e. at temperatures >900°C).

- **WEEE exported to third countries or remains unaccounted for**:

  A large fraction of the total flow of end-of-life EEE is not disposed of as household waste nor as WEEE but traded as second hand EEE. The fate of MCCPs contained in exported WEEE is

[33] Assuming that the amount of end-of-life EEE generated in a given year roughly equals that of EEE products being placed on the EU market in the preceding years.

[34] It needs to be born in mind that old EEE (i.e. second hand goods) destined for reuse do not enter the WEEE collection as long as they circulate on the second hand market. Thus, re-used EEE (and the materials contained therein) are technically not subject to WEEE accounting. As for the domestic second-hand market, this results merely in delay of WEEE generation whereas second-hand EEE exported outside the EU drops out of the European WEEE accounting.

unclear but a release into the environment (air) cannot be ruled out if cable scrap is subjected to open burning at uncontrolled temperatures (further elaborated in section 5.5).

To conclude on the MCCP releases from WEEE treatment inside EU, first of all it should be noted that, from WEEE that is incinerated conformal, no releases should be expected. However, during recycling, releases are possible. From WEEE that is collected and treated as municipal solid waste also no releases are expected as this waste is incinerated as well even though this is not the correct way of disposal. If ever, EEE are reused, after their second (or more) re-use phases, EEE end up in either the WEEE disposal route or the municipal solid waste. No releases are expected during the use phase. Finally, non-EU disposal routes (export & open buring) are the sources for most of the MCCPs emissions globally, as elaborated in the next section..

Other release routes are formulation, conversion, and re-use of PVC recyclate, however releases from re-use can be neglected.

5.5. Collection and treatment of electrical and electronic equipment outside EU

In the discussion on end-of-life management of products containing hazardous substances, it is often argued that recycling and disposal of WEEE is conducted under controlled conditions in the EU with no significant emissions of hazardous substances to the environment.

Nevertheless, it needs to be recognised that a significant share of WEEE is not collected and rather traded outside the EU. The transboundary trade is understood to be not transparent and partly illegal. Old EEE that is traded as second hand goods or products for repair and reuse does not fall under the WEEE directive because they are not considered waste. Even products that are damaged beyond repair are often not declared as waste and rather exported as second hand goods. Since the average WEEE collection rates have been below 50 % in the EU average in 2016 (see Figure 5-2), one must assume that the legal trade of second-hand EEE as well as illegal exports of WEEE towards receiving countries outside the EU occurs.

According to the outcomes of an EU financed research study on illegal WEEE trade (Huisman et al. 2015), only 35 % of WEEE generated in the EU28 plus Norway and Switzerland was collected and recycled under controlled conditions in 2012. Although another 23 % was also collected, subsequent treatment was considered to be non-compliant with the European WEEE-Directive. 750,000 tonnes (8 %) were estimated to have been disposed via the general household waste bin and treated as MSW. From the undocumented 3.2 million tonnes (34 % of total), it was estimated that 1.7 million tonnes have been processed within the EU and 1.5 million tonnes exported from the EU (see Table 5-2 and Table 5-3).

Table 5-2: Management pathways of WEEE in the EU28 plus Norway and Switzerland in 2012

Management path	Volumes [Million t]	Volumes [% of total]
Collected and recycled	3.3	35 %
Disposed with household waste	0.75	8 %
Collected and processed under non-compliant conditions	2.2	23 %
Undocumented	3.2	34 %
Total	9.45	100 %

Source: (Huisman et al. 2015)[35]

Table 5-3: Pathways of undocumented WEEE generated in the EU28 plus Norway and Switzerland in 2012

Pathway of undocumented WEEE	Volumes [Mio t]	Volumes [% of total]	Sub-pathways of undocumented WEEE	Volumes [Mio t]	Volumes [% of total]
Processed in the EU	1.7 Mio. t	18 %	Non-compliant processing	0.95 Mio. t	10 %
			Scavenged and stolen parts	0.75 Mio t	8 %
Exported from the EU	1.5 Mio. t	16 %	Documented exports of used equipment	0.2 Mio t	2 %
			Undocumented exports of used equipment	0.9 Mio t	10 %
			Undocumented export of WEEE	0.4 Mio t	4 %

Source: (Huisman et al. 2015)

These figures indicate that a significant share of WEEE – including cables and other components with contents of MCCPs – ends up in countries where WEEE is treated and disposed of by means of very crude technologies that entail environment and human health damage.

With regards to cables, this of particular concern because it is usually performed by open burning of cables in order to liberate the metal wires (mostly copper) from their insulation material. The practice of open cable burning has been observed in many countries, but in particular in countries with a strong dominance of an unregulated recycling sector such as Ghana and Nigeria (Manhart

35 Huisman, J.; Botezatu, I.; Herreras, L.; Liddane, M.; Hintsa, J.; Di Luda Cortemiglia, V. et al. (2015): Countering WEEE Illegal Trade (CWIT) Summary Report, Market Assessment, Legal Analysis, Crime Analysis and Recommendations Roadmap. Lyon. Online verfügbar unter http://www.cwitproject.eu/wp-content/uploads/2015/09/CWIT-Final-Report.pdf, last viewed: 17.07.2018.

et al. 2011[36]; Prakash und Manhart 2010[37]; Atiemo et al. 2016[38]). At the same time, West-African countries are also known to be major destinations for used EEE and WEEE exports from the EU. According to (Odeyingbo et al. 2017[39]) 77 % (around 56,000 t/a) of all imports of used equipment into Lagos (Nigeria) originated from EU countries (Amoyaw-Osei et al. 2011)[40] estimated that open cable fires in five West-African countries (Nigeria, Benin, Ghana, Côte d'Ivoire, Liberia) cause total dioxin (PCDD/F) emission equivalent to 3 %-7 % of total EU dioxin emissions to air in 2005.

Regarding the applied practices, recent research and co-operation projects – and in particular the Swiss funded SRI project[41] – found out that cable burning is mostly applied for waste cables with one or more of the following criteria:

- Short cables
- Thin cables
- Cables with no massive core
- Dirty cables
- Twisted cables

For such cables, mechanical liberation of metal wires (so called stripping) is economically unattractive as this would either demand quite significant labour input, or investments and running costs for recycling machines such as cable granulators. In this situation, open burning is – from an economic perspective – more attractive to recyclers (Buchert et al. 2016).[42] Thus, in many developing countries, mechanical cable stripping is only applied for long and quite thick cables with massive cores (e.g. overland power cables). Cables from EEE mostly fulfil the above listed criteria and are likely to be burned in informal sector settings.

In conclusion, the MCCP contained that unaccounted for amounts of WEEE or second-hand EEE that is traded outside the EU, is very likely to undergo open burning under crude conditions (no emission controls applied, absence of occupational health protection, inadequate disposal of residues). Uncontrolled heating and burning of MCCP bearing plastics at low temperatures (<900°C) can lead to the formation of dibenzo-p-dioxins and furans, in particular in the presence of copper. Another combustion product is hydrochloric acid (HCl), a highly acidic fume that causes respiratory problems if inhaled without protective gear. However, this pollution potential is not

36 Manhart, A.; Osibanjo, O.; Aderinto, A.; Prakash, S. (2011): Informal e-waste management in Lagos, Nigeria - socio-economic impacts and feasibility of international recycling co-operations. Final report of component 3 of the UNEP SBC E-waste Africa Project. Lagos & Freiburg.

37 Prakash, S.; Manhart, A. (2010): Socio-economic assessment and feasibility study on sustainable e-waste management in Ghana. Öko-Institut e.V. Freiburg. Online verfügbar unter http://www.oeko.de/oekodoc/1057/2010-105-en.pdf, last viewed: 12.11.2015.

38 Atiemo, S.; Faabeluon, L.; Manhart, A.; Nyaaba, L.; Schleicher, T. (2016): Baseline Assessment on E-waste Management in Ghana. Accra.

39 Odeyingbo, O.; Nnorom, I.; Deubzer, O. (2017): Person in the Port Project - Assessing Import of Used Electrical and Electronic Equipment into Nigeria. Bonn. Online verfügbar unter http://collections.unu.edu/eserv/UNU:6349/PiP_Report.pdf, last viewed: 17.07.2018.

40 Amoyaw-Osei, Y.; Agyekum, O. O.; Pwamang, J. A.; Mueller, E.; Fasko, R.; Schluep, M. (2011): Ghana e-Waste Country Assessmen. Accra. Online verfügbar unter http://ewasteguide.info/files/Amoyaw-Osei_2011_GreenAd-Empa.pdf, last viewed: 10.12.2015

41 See: https://www.sustainable-recycling.org/

42 Buchert, M.; Manhart, A.; Mehlhart, G.; Degreif, S.; Bleher, D.; Schleicher, T. et al. (2016): Transition to sound recycling of e-waste and car waste in developing countries - Lessons learned from implementing the Best-of-two-Worlds concept in Ghana and Egypt. Freiburg. Online verfügbar unter https://www.oeko.de/oekodoc/2533/2016-060-en.pdf, last viewed: 17.07.2018.

specific to MCCP but also occurs for PVC as such, because the polymer consists of chlorine too. However, the presence of MCCPs in PVC cable insulation increases the chlorine content and adds to the problem.

In more recent data from EUROSTAT (2019), the collection rate of WEEE was found to be 49 % of the EEE put on the market. A detailed breakdown of numbers to the categories presented in Huisman et al. (2015) was not carried out since then. However, the share of WEEE and EEE second hand goods exported to non-European countries is still considered to be a significant number.

Questions for stakeholders participating in the stakeholder consultation:

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

6. EXPOSURE ESTIMATION DURING USE AND/OR DURING WEEE TREATMENT

For the exposure estimation applying modelling tools, the estimations made by KEMI (2018) have been reviewed and can be followed. Beyond that, this section on exposure puts effort into the compilation of additional data that has not been brought into the discussion so far.

6.1. Human exposure estimation

6.1.1. Exposure of workers of WEEE processing plants

The following WEEE treatment activities are relevant for estimating the exposure to MCCPs at the working place:

- 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.

Incineration plants are not considered for the exposure of workers to MCCPs, as the substances are destroyed during incineration under controlled conditions.

Exposure estimation for workers was modelled by KEMI (2018) in the course of the preparation of the dossier at hand by using the ECETOC's Targeted Risk Assessment (TRA)[43] tool. It helps calculating the risk of exposure from chemicals to workers, consumers and the environment. The ECETOC TRA tool is intended for manufacturing and formulation processes, appropriate processes to describe the exposure conditions of waste treatment processes are available so far. The process category 24: "*high (mechanical) energy work-up of substances bound in materials and/or articles*" has been selected to calculate the exposure of workers of EEE waste processing plants. This approach was first introduced by the Austrian Umweltbundesamt for the RoHS assessment of the phthalates DEHP, DBP and BBP; it has also been used by the Fraunhofer ITEM IPA for TBBP-A.[44]

[43] European Centre for Ecotoxicology and Toxicology of Chemicals' Targeted Risk Assessment 3; http://www.ecetoc.org/tools/targeted-risk-assessment-tra/

[44] Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018): Assessment of TBBP-A (tetrabromopisphenol-A) according to the "Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex III) under the RoHS2 Directive". Update August 2018. Fraunhofer ITEM, Fraunhofer IPA, Stuttgart.

Table 6-1: Input parameters used in ECETOC TRA modelling

Scenario name	Shredding of separately collected WEEE and PVC cable waste	Formulation and conversion of PVC recyclate
Process categories	24a, b, c	2, 3, 4, 8a, 8b, 14 (for both); plus 1 and 15 for formulation; plus 6 and 21 for conversion
Treatment setting	Professional	Industrial
Duration of activity	>4 hours/day	>4 hours/day
Use of ventilation	Outdoors	Indoor with LEV
Respiratory protection	No	No
Substance in preparation	<1 % (WEEE) 1-5 % (PVC cable waste)	1-5 % (formulation) 5-25 % (conversion into new material)

Source: KEMI (2018)

The consultants of this review study can follow the estimations of KEMI (2018) [45] both in relation to the methodology applied and the scenarios and parameters used. In the figure below, the long-term exposure estimates are copied for inhalative and dermal exposure because for these scenarios corresponding DNELs exist that can be compared with.

The highest exposure estimations incur for the following scenarios:

- For Long-term Inhalative Exposure, the shredding processes resulted in the highest estimates:
  - Shredding of WEEE collected separately (24c): 1.40 mg/m^3
  - Shredding of PVC cable waste (24c): 2.80 mg/m^3

  It was assumed that the substance was a solid with medium dustiness. It should however be noted, that the subcategory “c” assumes a high fugacity, which means that the process temperature is higher than the melting point of the substance; as MCCPs are a UVCB there is no distinct melting point but commercial MCCP mixtures gradually soften when heated over a certain range of temperature levels. Thus, the subcategory assuming a high fugacity could result in an overestimation.
- For Long-Term Dermal exposure, Conversion of PVC recyclate (6) resulted in a high estimate of 16.5 mg/kg/day.

In order to further evaluate the estimates, workplace measurements have been investigated. However, no workplace measurements in WEEE processing plants has of yet been available.

45 Op. cit. KEMI 2018, table 44 in Annex I

Figure 6-1: Exposure estimates by ECETOC TRA as performed by KEMI

Scenario name (PROC #)	Long-term Inhalative Exposure Estimate (mg/m³)	Long-term Dermal Exposure Estimate (mg/kg/day)
Shredding of WEEE collected separately (24a)	2.10E-01	2.83E-01
Shredding of WEEE collected separately (24b)	3.50E-01	2.83E-01
Shredding of WEEE collected separately (24c)	1.40E+00	2.83E-01
Shredding of PVC cable waste (24a)	4.20E-01	5.66E-01
Shredding of PVC cable waste (24b)	7.00E-01	5.66E-01
Shredding of PVC cable waste (24c)	2.80E+00	5.66E-01
Formulation of PVC recyclate (1)	2.00E-03	6.86E-03
Formulation of PVC recyclate (2)	2.00E-04	2.74E-01
Formulation of PVC recyclate (3)	2.00E-03	1.37E-01
Formulation of PVC recyclate (4)	5.00E-01	1.37E+00
Formulation of PVC recyclate (8a)	1.00E+00	2.74E+00
Formulation of PVC recyclate (8b)	2.50E-01	2.74E+00
Formulation of PVC recyclate (14)	2.00E-01	6.86E-01
Formulation of PVC recyclate (15)	1.00E-01	6.86E-02
Conversion of PVC recyclate (2)	6.00E-04	8.23E-01
Conversion of PVC recyclate (3)	6.00E-03	4.11E-01
Conversion of PVC recyclate (4)	3.00E-02	4.11E+00
Conversion of PVC recyclate (6)	6.00E-03	1.65E+01
Conversion of PVC recyclate (8a)	3.00E-02	8.23E+00
Conversion of PVC recyclate (8b)	3.00E-03	8.23E+00
Conversion of PVC recyclate (14)	6.00E-03	2.06E+00
Conversion of PVC recyclate (21)	6.00E-02	1.70E+00

Source: KEMI (2018)

6.1.2. Exposure of neighbouring residents of EEE waste processing plants

Monitoring data for air would be necessary in order to estimate local exposure of neighbouring residents of EEE waste processing plants. However, there was no such data found during the preparation of this dossier.

6.1.3. Consumer exposure

KEMI (2018) does not consider consumer exposure to MCCPs as currently being relevant in this case, but points out that this might need to be evaluated in the future. For the current assessment, a number of analysis of indoor air and indoor dust have been found and reviewed:

- Wong et al (2017)[46] analysed selected dust samples from offices, homes and non-residential buildings in several countries. The highest concentration of chlorinated paraffins was measured in dust from China with a mean of 3044 µg/g. According to the authors, this may be due to the fact that China is the biggest producer of chlorinated paraffins. Chlorinated paraffins in dust in samples from Australia, the United Kingdom, Canada and Sweden ranged from 280 to 1330 µg/g. The pattern of congeners measured in the dust samples differ. In the dust from Australia, Canada and UK, C14 congeners were predominant and C15 congeners were the second most predominant.
- Dust analysis from private homes in Stockholm from 2018[47] showed that MCCPs with a median concentration of 31 µg/g dust was found; thus MCCPs were detected in higher concentrations compared to other chlorinated paraffins LCCPs and SCCPs (with a median concentration of 20 and 13 µg/g dust).
- A review on "chlorinated paraffins in indoor dust samples" (Coelhan and Hilger 2014)[48] reported data from Hamburg and Munich: Accordingly, MCCPs were detected in concentrations of 36 and 400 µg/g dust.
- As for indoor air measurements, Coelhan and Hilger (2014) report one study that measured MCCPs in indoor air at a median concentration of 69 ng/m^3 and a range from <5 to 210 ng/m^3.

The data presented here underlines that consumers, especially little children, are exposed to MCCPs that are released from articles. The impact arising from this exposure is discussed in section 7.3.

6.2. Environmental exposure estimation

KEMI (2018) uses the EUSES tool[49] to estimate the predicted environmental concentrations (PECs); the evaluation was carried out for all relevant waste management processes, i.e. shredding, formulation and compounding, incineration and landfilling, which will be summarized. Additionally to the exposures from models as performed by KEMI (2018), environmental monitoring data for MCCPs are compiled from information provided by the Norwegian Environment Agency[50] and from information specified in Glüge et al. (2018).

---

46 Wong, F., Suzuki, G., Michinaka, C., Yuan, B., Takigami, H., de Wit, C.A. (2017): Dioxin-like activities, halogenated flame retardants, organophosphate esters and chlorinated paraffins in dust from Australia, the United Kingdom, Canada, Sweden and China, Chemosphere, 168,(1248).

47 WSP Environmental Sverige (2018): Indoor Pollutants In Dust From NonHazCity Pilot Families In Stockholm, Test Report On Dust Campaign, Report from Work in GoA 5.4 "Test your environment".

48 Coelhan, M., Hilger, B. (2014): Chlorinated Paraffins in Indoor Dust Samples: A Review; Current Organic Chemistry 2014, 18, 2209- 2217.

49 European Union System for the Evaluation of Substances

50 Norwegian Environment Agency (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Norwegian_Environment_Agency_TBBPA_MCCPS_20180614.pdf, last viewed 24.07.2018

KEMI (2018) performed EUSES estimations for releases of MCCPs during WEEE treatment on the local and regional scale. The estimations for the regional PEC, which aggregates the releases from different WEEE processes, are shown in the table below.

Direct releases occur initially to air and water, but due to the MCCPs persistence and the environmental distribution of emissions, it is estimated to be found in all environmental compartments.

Table 6-2: PEC values for MCCP releases as estimate by EUSES on the regional scale

Regional PEC according to EUSES calculations	Value
Regional PEC in surface water (total)	6.37×10^{-5} mg/l
Regional PEC in seawater (total)	5.91×10^{-6} mg/l
Regional PEC in surface water (dissolved)	3.38×10^{-5} mg/l
Regional PEC in seawater (dissolved)	4.56×10^{-6} mg/l
Regional PEC in air (total)	1.21×10^{-6} mg/m^3
Regional PEC in agricultural soil (total)	0.872 mg/kg ww
Regional PEC in pore water of agricultural soil (total)	8.39×10^{-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

Source: KEMI (2018)

For the estimations in environmental compartments, no corresponding monitoring data are available. There are some environmental monitoring data for MCCPs that are compiled from information provided by the Norwegian Environment Agency.[51] The monitoring data target to a lesser extent different environmental compartments - besides air – but rather biota. These data show that MCCPs have been detected in the air and different biota (see the following Table 6-2).

51 Norwegian Environment Agency (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Norwegian_Environment_Agency_TBBPA_MCCPS_20180614.pdf, last viewed 24.07.2018

Table 6-3: Monitoring data from Norway

Env. compartment / biota	MCCP levels	Source
Air	30 – 130 pg/m^3	Monitoring of environmental contaminants in air and precipitation 2014; http://www.miljodirektoratet.no/Documents/publikasjoner/M368/M368.pdf Monitoring of environmental contaminants in air and precipitation 2015; http://www.miljodirektoratet.no/Documents/publikasjoner/M579/M579.pdf Monitoring of environmental contaminants in air and precipitation 2016; http://www.miljodirektoratet.no/Documents/publikasjoner/M757/M757.pdf
Trout	<0.5 – 1.8 ng/g	Environmental pollutants in large Norwegian lakes, 2016; http://www.miljodirektoratet.no/Documents/publikasjoner/M807/M807.pdf
Perch	<0.5 – 3.1 ng/g	
Cod liver	32.3 - 131.0 (931.5) µg/kg ww (2012) 292 - 1202 µg/kg ww (2015) 154 - 1850 µg/kg ww (2016)	Contaminants in coastal waters of Norway (Milkys) 2012; http://www.miljodirektoratet.no/Documents/publikasjoner/M69/M69.pdf Contaminants in coastal waters of Norway (Milkys) 2015; http://www.miljodirektoratet.no/Documents/publikasjoner/M618/M618.pdf Contaminants in coastal waters of Norway (Milkys) 2016; http://www.miljodirektoratet.no/Documents/publikasjoner/M856/M856.pdf
Blue mussel	2.4 - 17.9 µg/kg ww (2012) 11.1 – 115 µg/kg ww (2015) 24.2 – 114 µg/kg ww (2016)	

Source: Norwegian Environment Agency (2018)

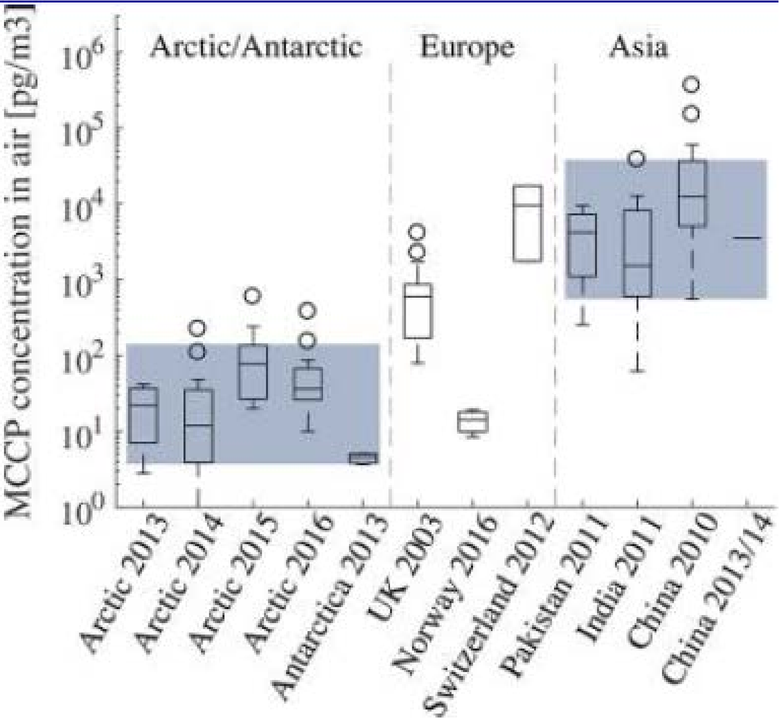
For cod liver and blue mussels, there are measurements for the years 2012, 2015 and 2016. The Norwegian Environment Agency itself has not evaluated the trends over the time of the MCCPs concentrations in the biota. Though in the current assessment, a statistical evaluation was not performed, it can be observed that that the ranges of the MCCPs concentrations measured increased over the years cod liver as well as blue mussel. Under the understanding that mussels would be at a lower level within the food chain than cod further suggests that the concentrations of MCCPs accumulate throughout the food chain.

Not all MCCPs in the environment derives from EEE but also from other applications, however an increasing MCCPs contamination in biota can be concluded from the Norwegian monitoring data.

6.2.1. Monitoring data: remote regions, biota

In contrast to the findings of KEMI (2018) that there has been no monitoring data of MCCPs in remote regions, the review of Glüge et al. (2018) summarizes several findings of MCCPs in remote areas. MCCPs concentration in the air measured in the Arctic and Antarctic region, in comparison to e.g. concentrations measured in Europe, are shown in the following figure.

Figure 6-2: MCCPs concentrations in air



Source: Glüge et al. (2018); the blue rectangles indicate the MCCP concentration ranges in the specific regions. The data from the Arctic are only semi quantitative.

As for biota, Glüge et al. (2018) reported findings in fish and birds where measurements are also available from the Arctic. Glüge et al. (2018) concluded that the relatively high MCCP concentrations found in Arctic fish show once more that MCCPs are able to undergo long-range atmospheric transport, and that the MCCP concentrations in bird eggs and bird tissue were in the same range or slightly lower than the SCCP concentrations measured in the same animals and at the same points in time.

In their position paper[52], EuroChlor questioned the monitoring results stating that *“several of the studies, relied upon as part of the proposal, are also questionable. These studies utilise old methods that cannot effectively distinguish between Short Chain Chlorinated Paraffins (SCCP, a controlled substance in the EU) and MCCP. These older methods relied on laboratory produced technical standards that bear little chemical resemblance to any products ever placed on the market, adding to their inconclusive findings. Only by applying modern methods (see van Mourik et al. 2015) can such molecules be accurately quantified in biological or environmental samples.”*

Glüge et al. (2018)[53] discussed the sources of errors in the measurements for occurrence of MCCPs in the environment, biota, and humans. They summarised the studies *“Taking all the other possible error sources into account”, “we have to assume that most of the reported concentrations might not be very accurate. We believe, however, that the overall picture from the whole set of measurements and studies is (at least at the order of magnitude) correct and will give valuable insights into the environmental contamination with MCCPs.”* Glüge et al. (2018) concluded: *“If we*

52 Opt. cit. EuroChlor (2018)

53 Opt. cit. Glüge et al. (2018)

look at the obtained overall picture of the environmental contamination with MCCPs, we see that MCCPs have been detected in all environmental compartments as well as in fish, birds, mammals, and human tissues, and they are often measured in higher concentrations than SCCPs. Most alarming to us are the sediment concentrations that reach or exceed the PNEC in sediment, as well as the increasing time trends observed for the MCCPs in various locations worldwide. We also observe the potential of the MCCPs to undergo long-range atmospheric transport and their high potential for chronic toxicity to aquatic invertebrates."

In the consultants view the data uncertainties have been sufficiently taken into consideration in the Glüge et al. (2018)[54] data. The increase in sampling data for biota provided in the Norwegian data also strengthens the concerns raised by Glüge in relation to the increasing time trends observed for MCCPs worldwide. Though it may be argued what the range of impact is, the understanding that MCCPs may be classified as vPvB[55] suggests that a precautionary approach may be relevant here.

6.3. Exposure under uncontrolled disposal

If incineration does not take place under controlled conditions, the presence of chlorinated paraffins can give rise to hazardous reaction products. In case of uncontrolled fires (accidental fire) and at co-combustion at lower temperatures or not well functioning incinerators, chlorinated paraffins can be a source of chlorine, subsequently leading to the formation of polychlorinated dioxins and furans. Furthermore unsaturated hydrocarbon products, including aromatic products such as polychlorinated biphenyls and polychlorinated naphthalene, can also be formed under certain circumstances, such as under heat or in contact with alkaline substances (Oeko-Institut, 2008).[56]

The informal cable treatment (open cable burning), though not common in the EU, is a massive human health issue for the workers and the local population. Furthermore, this will also be addressed in the impact and risk evaluation section under risk for the environment.

7. IMPACT AND RISK EVALUATION

The substance evaluation of the human health and environment hazards of MCCPs is currently still in progress. However, according to the "Brief report from the 22nd PBT EG meeting (Helsinki, 3-4 September 2019)" [57], the general view is that MCCP at or above 50 % chlorine by weight are vPvB. This conclusion heavily affects the impact and risk evaluation here at hand because as a result of both properties, the current DNELs and PNEC would no longer be applicable.

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

There is information lacking especially on actual amounts of MCCPs entering the European market through the import of articles. Thus, the actual amount entering the waste cannot properly be estimated. The assessment in section 5 is generally based on the assumption of an annual MCCP

[54] Opt. cit. Glüge et al. (2018)

[55] See footnote 57.

[56] Oeko-Institute (2008): Study on Hazardous Substances in Electrical and Electronic Equipment, not Regulated by the RoHS Directive

[57] https://echa.europa.eu/documents/10162/21877836/Brief_report_PBTEG22.pdf/647a3dc4-6bcc-e2b7-5d29-c4b0945a0d37, last viewed 20.11.2019

consumption of 15,000 t in EEE in the EU plus an amount X entering the EU through imported EEE articles.

However there are no evidences found that the actual MCCP content in WEEE plays any role for the treatment processes, respectively there were no interferences found in WEEE processes related to the presence of MCCPs. PVC recycling is possible and increasingly applied independent from the MCCP content in the polymer as can be understood from the claims of industry, e.g. projects like VinylPlus.

Informal recycling and its problems associated with MCCPs are subsumed to risks to the environment.

7.2. Risks for workers

Based on the estimations derived from ECETOC and in order to derive a risk characterisation ratio (RCR), KEMI (2018) compared the exposure estimation values to the most stringent DNEL values that have been given in the EU RAR (2008) and not to those DNELs that have been provided by the REACH registrants (see section 3.2).

The findings lead to two relevant scenarios (with RCRs >1) where risks are not adequately controlled, that are:

- The shredding of PVC cable waste (PROC 24c), taking a DNEL for inhalative exposure at 1.6 mg/m^3, the inhalation RCR is at 1.75; no respiratory protection equipment or gloves were considered in the assessment by KEMI (2018) as these are not used uniformly; and
- The conversion of PVC recyclate (PROC 6) through dermal exposure during calendering operations with temperatures higher than the ambient; the RCR – assuming a DNEL for long term dermal exposure at 11.5 mg/kg bw/day – is at 1.43.

The findings from KEMI (2018) differ from the EU RAR as the latter did not identify an unacceptable risk to workers' health under all PVC-related scenarios examined (formulation/manufacture, calendering, compounding, extrusion/moulding).

Generally estimations gained by ECETOC are rather used for workplace management and for concluding whether protection measures have to be established. Thus, the results indicate that an exposure by MCCPs in WEEE recalling plants occurs and protection routines in the waste recycling plants in Europe have to be installed.

It should however be noted that a classification of MCCPs as vPvB would also effect the DNEL for human health; thus the risk for workers arising from shredding of PVC cable waste and conversion of PVC recyclate expected under the current classification may need to be revised in the case of a classification as future DNELs cannot anticipated here.

7.3. Risks for consumers and neighbouring residents

The data show that MCCPs are ubiquitously present in indoor air and indoor dust. The indoor dust can be inhaled. House dust itself may also lead to dermal exposure and in small children to oral exposure due to mouthing behaviour.[58] A conservative estimate of 100 mg/day has been proposed

[58] European Chemicals Agency ECHA (2015): Guidance on Information Requirements and Chemical Safety AssessmentChapterR.15: Consumer exposure estimation; Draft (Public)Version 3.0 October 2015;

for house dust intake for children (Oomen, et al., 2008).[59] The uptake can then be calculated by multiplying the measured concentrations with dust uptake defaults. As body weight for children, 10 kg is assumed (body weight assumption in ECETOC TRA v.3 model according to Wibbertmann and Hahn 2018).[60] The DNEL for the general population for long term oral exposure has been indicated at 580 µg/kg bw/day by the REACH registrants. Taking this current DNEL, no risk for children by MCCPs in house dust can be derived (see results in the table below).

Table 7-1: MCCPs concentrations in house dust in Europe and the derived long-term oral exposure of children

Range in dust measurements	Long-term oral exposure of children assuming 10 kg body weight
31 – 464 µg/g	0.031 – 0.464 µg/kg/day

Source: Own compilation; dust measurements from WSP Environmental Sverige (2018) and Wong et al. (2017) for the UK

However, as the substance evaluation of MCCPs is currently not finished, the general exposure of consumers by house dust is to be considered to raise some concern: the vPvB properties can lead to accumulation where current values are exceeded. Even more as for the human health hazard, there is a harmonized classification for MCCPs indicating “May cause harm to breast-fed children”. Thus, a general risk that MCCPs may affect the human health cannot be ruled out.

7.4. Risks for the environment

From the regional predicted environmental exposure estimations gained by EUSES, there are some processes that indicate an environmental risk: PVC formulation and conversion, as well as landfilling of WEEE and PVC waste and incineration leads to MCCPs releases that exceeds the PNECs of some environmental compartments:

According to KEMI (2018) risks are identified;

- By formulation of PVC for the sediment, marine water and for secondary poisoning via the earthworm food chain;
- By conversion of PVC for freshwater, sediment, marine water and for secondary poisoning via the earthworm food chain (4.10);
- By landfilling of WEEE and PVC waste for sediment and for secondary poisoning via the earthworm food chain; and
- By incineration of WEEE and PVC waste: secondary poisoning via the earthworm food chain.

To conclude, WEEE treatment as performed in Europe results in risks for the environment despite the conclusion not taking into account the vPvB properties recently described by the ECHA PBT expert group and the pending classification.

https://echa.europa.eu/documents/10162/23047722/draft_201510_r15_peg_infreq_uses_en.pdf/4c52b39e-ca5e-4cb2-a6e3-b8020dc8d047, last viewed 20.11.2019

59 Oomen, A.G.; Janssen, P.J.C.M.; Dusseldorp, A.; Noorlander, C.W. (2008): Exposure to chemicals via house dust; https://www.rivm.nl/bibliotheek/rapporten/609021064.html

60 Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018): Assessment of TBBP-A (tetrabromopisphenol-A) according to the “Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex III) under the RoHS2 Directive”. Update August 2018. Fraunhofer ITEM, Fraunhofer IPA, Stuttgart.

Additionally, the collection and treatment of electrical and electronic equipment outside EU with regards to cables has a special human health and environmental risk aspect. In the context of PVC cables, uncontrolled burning - in order to liberate the metal wires (mostly from copper) from their insulation material - and thus releases of halogenated compounds entail the formation of halogenated dioxins and furans with health implications for workers. In addition, the applied storage and treatment practice result in a release of chemicals incorporated in the WEEE. This is of utmost interest in the case of (potential) PBT/vPvB substances as is the case for MCCP. The practice of open cable burning has been observed in particular in West-African countries with a strong dominance of informal sector recycling. There are estimates that open cable fires in five West-African countries (Nigeria, Benin, Ghana, Côte d'Ivoire, Liberia) cause total dioxin (PCDD/F) emission equivalent to 3 %-7 % of total EU dioxin emissions to air in 2005 (see section 5.5). This number shows that there is a considerable contribution of dioxin emissions.

Against the background, that MCCPs have recently been considered for being vPvB in the ECHA PBT expert group, these releases have to be considered.

Hence, there is evidence that MCCPs can be considered as a global pollutant as it can be measured in various environmental compartments and also in organisms at high trophic levels.

The findings of MCCPs concentrations in remote regions far from emission sources support the presumption of MCCPs or at least certain compounds with a high chlorine content being very persistent substances. The bio-accumulative property is based on MCCPs measurements in various environmental compartments and also in organisms at high trophic levels. In light of global supply chains and the potential for long-range transport, releases of PBT/vPvB substances are not only of relevance if occurring locally. They are also to be considered as bioaccumulation takes place mainly in the food chain and various produce is imported to the EU from countries where WEEE and second hand EEE is exported to. It is not the focus of this work to quantify this exposure route and consequential risks. Though the emissions of MCCPs are not only due to the use in EEE under the scope of the RoHS directive, the monitoring data support the general concern on MCCPs.

8. ALTERNATIVES

8.1. Availability of substitutes / alternative technologies

Former studies came to the conclusion that there would be currently no one-to-one alternatives to MCCPs available on the market.[61] This is due to the fact that several requested properties can be attributed to MCCPs, which are flame retardancy, improved water and chemical resistance, enhanced viscosity, ageing stability, and finally, reduced formulation costs. In this light, alternatives should be based on product specific reformulations. However, PVC cable formulations have already undergone several phases where reformulations were necessary e.g.

- the phase out of heavy metals (Pb and Cd) as thermal stabilizer and PBDEs due to the introduction of the first RoHS Directive,
- the European ban of the four phthalates under REACH and RoHS 2 and
- the ban of SCCPs under the Stockholm Convention (respectively the EU POP regulation)

[61] Op. cit. KEMI (2018)

These changes all happened consecutively. It is therefore understood that PVC formulation and the use of additives is constantly under development to take into account restrictions. Industry itself describes a continuous adaptation of stabilizers[62] and plasticizers.

For the two main functions of MCCP, the plasticising as well as the flame retardant effect, alternatives are available. This may entail that more than one substance is needed to replace MCCPs in order to achieve desired material characteristics.

The following table lists main potential alternatives for the plasticising or flame retardant properties of MCCPs that can be used in soft PVC, besides long chain chlorinated paraffins (LCCPs), certain phthalates (e.g. DINP) and several phosphate esters as well as diantimony trioxide and metal hydroxides such as aluminium hydroxide and magnesium hydroxide.

Table 8-1: Plasticising and/or flame retardant properties and production/import volume of alternatives

Substance	CAS	Plasticiser	Flame retardant	Production and import volume in the EU
Long-chain chlorinated paraffins (LCCPs)	63449-39-8	Yes	Yes	High registered tonnage 10,000-100,000 tpa
Phthalates, e.g. DINP	28553-12-0	Yes	No	High registered tonnage of 100,000-1,000,000 tpa; *used as direct substitute of phthalates under pressure, e.g. DEHP*
Phthalates, e.g. DIDP	68515-49-1	Yes	No	High registered tonnage of 100,000-1,000,000 tpa; *used as direct substitute of phthalates under pressure, e.g. DEHP*
Adipates, e.g. Bis(2-ethylhexyl) adipate (DEHA, DOA)	103-23-1	Yes	No	Low registered tonnage of 1,000 – 10,000 tpa
Citrates, e.g. Acetyl tri-n-butylcitrate (ATBC)	77-90-7	Yes	No	High registered tonnage of 10,000 – 100,000 tpa
Trimellitates, e.g, Tris(2-ethylhexyl) trimellitate (TOTM)	3319-31-1	Yes	No	High registered tonnage of 10,000 – 100,000 tpa, Tonnage is expected to increase in the future given that the substance has

62 "Stabilisers formulations are being continuously adapted to anticipate on the regulatory context and with sustainability in the visor"; Cavallero, A. (2017): About PVC stabilisers and Sustainability, Dr. Alain Cavallero, European Stabiliser Producers Association, ESPA; 1st PVC4CABLES conference, 26 October 2017; https://www.pvc4cables.org/images/Cavallero.pdf, last viewed 25.09.2018

Substance	CAS	Plasticiser	Flame retardant	Production and import volume in the EU
				been highlighted as a substitute to a number of phthalates under regulatory pressure.
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	Low registered tonnage of 1,000 – 10,000 tpa
Triphenyl phosphate	115-86-6	Yes	Yes	Low registered tonnage of 1,000 – 10,000 tpa
Isodecyl diphenyl phosphate	29761-21-5	Yes	Yes	Low registered tonnage of 1,000 – 10,000 tpa e.g. Phosflex 390 by ICL
2-ethylhexyl diphenyl phosphate	1241-94-7	Yes	Yes	Low registered tonnage of 1,000 – 10,000 tpa
Bisphenol-A bisphosphate (BDP)	5945-33-5	Yes	Yes	Low registered tonnage of 1,000 – 10,000 tpa
Aluminium hydroxide	21645-51-2	No	Yes	High registered tonnage of 1,000,000 – 10,000,000 tpa
Magnesium hydroxide	1309-42-8	No	Yes	High registered tonnage 100,000 – 1,000,000 tpa e.g. FR-20 by ICL
Antimony trioxide	1309-64-4	No	Yes	Usually used as a synergist in combination with halogenated flame retardants; supports the inherent flame retardancy of PVC.

Source: KEMI (2018) and own additions

The following table summarises halogen-free flame retardants used in cable compounds as compiled in the Oeko-Institut report of 2008 updated with more current information gained from stakeholder contributions. [63]

Table 8-2: Halogen-free flame retardants used in cable compounds

Flame retardant	Polymers	Flame retardancy effectiveness	Applications
Metal hydroxides, e.g. Aluminium trihydroxide (**ATH**) Magnesium dihydroxide (**MDH**) (Aluminium-oxide-hydroxide (**AOH**, boehmite)	**Polyolefins:** Low-density polyethylene (LDPE)	In fire, these mineral FRs decompose, absorbing energy, releasing water (reducing fire intensity	Electrical cables - Low voltage - Medium voltage

[63] Op. cit. Pinfa (2017) last viewed 24.07.2018.; op. cit. Kemi (2018)

Flame retardant	Polymers	Flame retardancy effectiveness	Applications
	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)**	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	- Photovoltaic (PV) cables - Emergency lighting Control cables - Fire alarm cables Information cables - LAN cables - Telephone cables
Zinc borate	See above	Synergist with ATH Zinc borate is a smoke suppressant that works in the condensed phase by forming a glass-like char.	See above
Zinc stannate and zinc hydroxystannates	See above	Synergist with ATH Zinc (hydroxy-)stannate works both in the gas phase (flame) and in the condensed phase (smoke) simultaneously	See above
Phosphorus based flame retardants			
Metal phosphinates, e.g. **Aluminium diethylphosphinate (Alpi)** and polyphosphonates	**Used in fire-resistant coatings for cables** - Polyolefins - Polypropylene (PP) **Elastomers:** - Thermoplastic Elastomers (TPE) - Thermoplastic Poly Urethanes - Thermoplastic Polyesters	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	Electrical cables - Photovoltaic (PV) cables Control cables - Lift cables - Fire alarm cables
Red phosphorus		See above	
Phosphate esters (e. g. Tricresyl Phosphate TCP)		See above	

Flame retardant	Polymers	Flame retardancy effectiveness	Applications
Ammonium polyphosphate (APP)		With loading of 15–30 % new developed products can achieve highest fire safety standards (UL 94 V0) by formation of an insulating fire barrier me retardants used in HFFR cable compounds.	
	Nitrogen flame retardants		
Melamine Derivatives (e.g. melamine cyanurate, melamine (poly)phosphate)	**Used in fire-resistant coatings for cables** - Polyolefins - Polypropylene (PP) **Elastomers:** - Thermoplastic Elastomers (TPE) - Thermoplastic Poly Urethanes - - Thermoplastic Polyesters	A low dosing between 7–15 % results in polymer decomposing (PA) without flaming	

Source: KEMI (2018); Oeko-Institut (2008); Pinfa (2017)

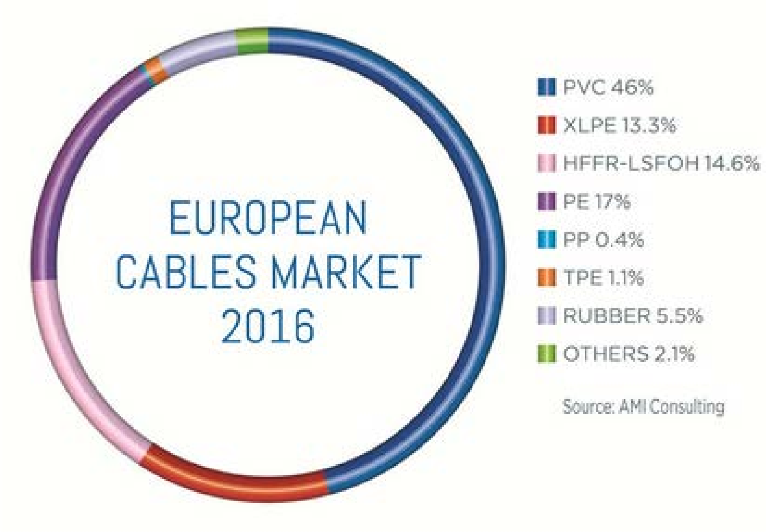
Furthermore, instead of substituting MCCPs, the use of alternative polymer materials, other than PVC, also enchain MCCP-free options: An advantage of alternative polymer materials that can be used for cable and wire insulation is the additional aim to phase-out halogenated flame retardants. Thus, this approach may apply to a set of substances that are already restricted by the RoHS Directive (such as PBDEs) as well as further substances that are also discussed for a possible restriction under RoHS such as diantimony trioxide which is used as synergist for halogenated flame retardants. Pinfa (2017) describes the following (MCCP-free) flame retarded thermoplastic elastomers for cable applications:

- Thermoplastic elastomers (TPE) consist of a thermoplastic urethane as monomer and copolyesters and polyether block amide. There are different TPE types with different desired properties. *“Metal phosphinates can effectively balance mechanical properties and flame retardancy in TPEs. Polyphosphonates have also been found to perform well in TPE-E systems.”*
- Copolyester elastomers are based on polybutylene terephthalate and polyether groups. Metal phosphinates finely grained provides flame retardancy with an addition of polyphosphonates or nitrogen synergists in some cases.
- Thermoplastic urethanes consists of hydroxyl terminated polyesters or polyethers and diphenylmethane diisocyanate. By adding 12-15 % metal phosphinate in fine grades with nitrogen synergists or by adding formulations containing melamine cyanurate, the classification UL 94 V-0 is achieved. Polyphosphonates are also used in specific applications where e.g.

transparency is desired and also work synergistically with melamine cyanurate and metal phosphinate for improved flame retardancy and mechanical properties.

The webpage of PVC4Cables, a platform of the European Council of Vinyl Manufacturers (ECVM) specifies the shares of polymer material used in cable sheeting and insulation on the European cable market as to see from Figure 8-2; however, it should be noted that these statistics cover all kind of cables not only the low voltage cables as used in EEE (and addressed here). In 2016, PVC held a share of just under 50 % while the former mentioned TPE only accounts for ~1 %. With ~15 %, HFFR-LSFOH is on the third position. These *"Halogen-Free Flame Retardant - Low Smoke and Fume, Zero Halogen Compounds"* can be based on poly-olefins (PP, PE)[64] and thermoplastic elastomers (e.g. PU). Here, flame retardancy is facilitated through Magnesium and Aluminium hydroxides.[65] With respect to this material, other stakeholders speak of a trend, e.g. Pinfa (2017) describes further developments in the field of metal hydroxides for the use in wire and cable applications.[66]

Figure 8-1: Share of polymers used in cable sheeting and insulation on the European cable market 2016 according to the European Council of Vinyl Manufacturers (ECVM)



Source: https://www.pvc4cables.org/en/pvc-cables/market

Abbreviations:

PVC – Polyvinylchloride; XLPE – Cross-linked polyethylene; HFFR-LSFOH – Halogen-Free Flame Retardant - Low Smoke and Fume, Zero Halogen Compounds (often olefins); PE – polyethylene; PP – polypropylene; TPE – thermoplastic elastomers

64 https://www.polyone.com/files/resources//EM_LSFOH_BU_Overview___75360.pdf (assessed 21.11.2019)

65 Anixter (2012) LOW SMOKE ZERO HALOGEN WIRE AND CABLE BEST PRACTICES https://www.anixter.com/content/dam/Anixter/White%20Papers/12F0003X00-Anixter-LSZH-WP-W%26C-EN-US.pdf (assessed 21.11.2019)

66 Pinfa (Phosphorus, Inorganic and Nitrogren Flame Retardants Association) (2017): Flame retardants in electric and electronic applications, non-halogenated phosphorus, inorganic and nitrogen (PIN) flame retardants; October 2017, 3rd edition; https://www.pinfa.eu/wp-content/uploads/2018/05/PINFA_EE_brochure_Edition_2017-11.pdf, last viewed 24.07.2018.

KEMI (2018) concludes that, overall, the use of alternatives would be likely to be *"associated with more specific, product-by-product reformulations, tailor-made in order to ensure optimised results for end-products."* The following table shows such concrete examples for MCCP-free PVC formulation with a set of the above mentioned plasticizers and flame retardants.

Table 8-3: MCCP-free PVC formulation for cable and wire

	Product / supplier
Plasticizer DINP; Stabilizer & Process Aid; Ecopiren 3.5C (magnesium hydroxide); Antimony Oxide or Antimony Oxide Replacement	Europiren
ESO (Drapex 6.8, epoxidised soybean oil), Stabilizer BaZn (Mark 6731, barium zinc), Plasticizer DIDP, ATH (Hydral 710), Calcium Carbonate (Atomite Whiting), Elvaloy® HP441 (ethylene/n-butyl acrylate), Antioxident (Irganox 1010, pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)), Antioxident (DLTDP, dilauryl thiodipropionate), TiPure® R960 (titanium dioxide)	DuPont

Source: Europiren: https://www.europiren.com/flame-retardants/ecopiren-pvc-wire-and-cable-formulations/, last viewed 25.09.2018; DuPont: http://www2.dupont.com/Elvaloy/en_US/tech_info/elvaloy_pvc_wire_and_cable.html#start, last viewed 25.09.2018

Certain companies restrict the use of MCCPs

The availability of alternatives becomes apparent by the fact that so called frontrunner companies where environmental management and health and safety are of strategic importance restrict the use of MCCPs, e.g.:

- Dell in its Specification on "Materials Restricted for Use",[67] Alkanes C14-C17, chloro, Medium Chain Chlorinated Paraffins (MCCPs) are restricted with a threshold limit of 1000ppm which is clearly below the concentration of the substance in preparation.

  It has to be noted however that Delll refers to the CAS number as specified for this dossier, which means that other chlorinated paraffins specified by different CAS numbers might be used.

- According to the Apple Regulated Substances Specification,[68] "Chlorinated Paraffins, Short and Medium Chain (SCCP and MCCP)" and as well "Chlorine and its compounds" and consequently "Polyvinyl Chloride (PVC)" are restricted substances in homogeneous materials used in Apple products with a limit threshold of 900 ppm Cl.

8.2. Hazardous properties of substitutes

As it was outlined earlier, two strategies are possible in terms of the substitution of MCCPs in EEE: first, substitution of MCCP in the existing polymer matrix for one or more other substances with flame retardant and plasticising properties; second, application of alternative polymer materials, other than PVC, in which desired properties can achieved without MCCPs.

Substances that fall under the category of the first substitution strategy are assessed in Table 8-4; other assessments are discussed in further detail thereafter. The assessment of the

[67] Dell (2018): Specification Materials Restricted for Use Revision: A03-00, Document Number: ENV0424; https://www.dell.com/learn/us/en/05/shared-content~solutions~en/documents~env0424-a02.pdf, last viewed at 24.07.2018

[68] Apple (2016): Apple Regulated Substances Specification 069-0135-J; https://www.apple.com/supplier-responsibility/pdf/Apple-Regulated-Substance-Specification.pdf, last viewed 24.07.2018

hazardousness of alternative polymer materials is not as easy as for concrete substances that are subject to registration under REACH as polymers do not have to be registered. Therefore no (eco-) toxicological data have to be submitted to ECHA before bringing the polymers onto the market. As a consequence, an assessment of hazardous properties of polymers mentioned in section 8.1 is not possible. Still a conclusion is drawn under 8.4.

The entries of Table 8-4 can be categorised to four groups due to structural similarities: (1) Long-chain chlorinated paraffins; (2) Alkyl-substituted carboxylic esters (phthalates, DEHA, ATBC, TOTM); (3) Organophosphate esters (OPE); (4) Inorganic FR (ATH, MTH, ATO). However, human and environmental risk can differ within a group and cannot be generalised. LCCPs are suspected of low human health risk; though, PBT properties cannot be excluded. Of the second category, ATBC seems to be the most promising candidate as the others are suspected of having several undesirable properties. For OPEs, the determining factor for an environmental or human health risk seems to be whether phenyl, cresyl and/or xylyl substituents are side chains to the phosphate. For a tri-substituted compound, there is a wide variety of substitution patterns; individual assessment of compounds leads to the conclusions that simplifications by grouping may not lead to a misleading picture. Discussing the inorganic FR, the hydroxides shall be preferred to diantimony trioxide.

Table 8-4: Hazardous properties of substitutes for MCCPs

Substance	CAS	Harmonised classification	Restrictions under REACH	Human Health Concerns	Environmental Concerns
Long-chain chlorinated paraffins (LCCPs)	63449-39-8	No harmonised classification	None	Low toxicity	Potentially persistent and bioaccumulative (but past assessments reach different conclusions)
Di-'isononyl' phthalate DINP	28553-12-0	No harmonised classification	Entry 52 Annex XVII: Restrictions to use in toys and childcare articles that can be placed in the mouth by children	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
Di-'isodecyl' phthalate DIDP	68515-49-1	No harmonised classification		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
Bis(2-ethylhexyl) adipate DEHA	103-23-1	No harmonised classification	Included in CoRAP in 2013	According to the CoRAP justification, [69] DEHA has been suspected of having effects on the male reproductive system because it shares similarities in chemical structure and metabolism with DEHP.	
Acetyl tri-n-butylcitrate (ATBC)	77-90-7	No harmonised classification	None	low acute toxicity, low or slight sensitising, no mutagenic activity and no reproductive effects;	readily biodegradable as well as ultimately biodegradable. Indications for bioaccumulation potential and potential for

[69] Finnish Safety and Chemicals Agency (Tukes), Finland (2013): Justification for the selection of a candidate CoRAP substance: bis(2-ethylhexyl) adipate; https://echa.europa.eu/documents/10162/ce16ad6d-513c-4aba-95c3-94276cecc2d2, last viewed 25.09.2018

Substance	CAS	Harmonised classification	Restrictions under REACH	Human Health Concerns	Environmental Concerns
					aquatic toxicity
Tris(2-ethylhexyl) trimellitate (TOTM)	3319-31-1	No harmonised classification	Added to CoRAP in 2012		According to substance evaluation decision, potential PBT/vPvB; tonnages and exposure are expected to increase in the near future.[70]
Cresyl diphenyl phosphate	26444-49-5	No harmonised classification	None	Chronic toxicant with effects on liver, kidney and blood. Effects on fertility	Readily biodegradable; toxic to aquatic organisms
Tricresyl phosphate	1330-78-5	No harmonised classification	Added to CoRAP in 2014	According to CoRAP justification, potential neurotoxic effects of (isomers of) TCP	According to CoRAP justification, (suspected) PBT[71]
Trixylyl phosphate	25155-23-1	Repr. 1B	SVHC included in Candidate list Added to CoRAP in 2014	According to substance evaluation decision, potential risk for secondary poisoning	According to substance evaluation decision,[72] suspected PBT/vPvB, high Risk Characterisation Ratio, potential risk for soil compartment and
Triphenyl phosphate	115-86-6	No harmonised classification	Added to CoRAP in 2013	According to CoRAP justification,[73] potential endocrine disruptor	
Isodecyl diphenyl phosphate	29761-21-5	No harmonised classification	None	there were several risks identified , which are however not further specified	
2-ethylhexyl	1241-94-7	No harmonised	None	no risk identified	

70 ECHA (2014): Decision on Substance Evaluation for tris(2-ethylhexyl)benzene-1,2,4-tricarboxylate; https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e4cae, last viewed 25.09.2018

71 ECHA (2016): Decisions on Substance Evaluation for Tris(methylphenyl) phosphate; see the different decisions for all Registrant(s) and separate decisions to individual Registrants at https://echa.europa.eu/de/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e180694747, last viewed 25.09.2018

72 ECHA (2016): Decisions on Substance Evaluation for Trixylyl Phosphate; https://echa.europa.eu/documents/10162/94e8d9c9-be37-6349-92ba-dddfac4122b5, last viewed 25.09.2018

73 UK CA (2013): Justification for the selection of a candidate CoRAP substance; https://echa.europa.eu/documents/10162/47fa7ee3-8323-4532-bb52-f1d8fe3b5ea4, last viewed 25.09.2018

Substance	CAS	Harmonised classification	Restrictions under REACH	Human Health Concerns	Environmental Concerns
diphenyl phosphate		classification			
Aluminium hydroxide	21645-51-2	No harmonised classification	None	no risk to human health	data gaps concerning environmental hazards
Magnesium hydroxide	1309-42-8	No harmonised classification	None	No further information	
Antimony trioxide	1309-64-4	Carc 2	None Added to CoRAP in 2018	According to CoRAP justification,[74] suspected CMR (reclassification for carcinogenicity may be necessary) and high Risk Characterisation Ratio	

Source: Op. cit. KEMI (2018) if not indicated differently; European Chemicals Agency ECHA, https://echa.europa.eu

[74] DE MSCA (2016): Justification Document for the Selection of a CoRAP Substance; https://echa.europa.eu/documents/10162/44adc62e-ff48-4ce8-9c4f-58dd8b77253a, last viewed 25.09.2018

In earlier works from other stakeholders, there have been different methodological assessment approaches. Two of those will be summarised in the following focussing on their overall conclusions. However, it should be noted, that both concentrate on flame retardants rather than on plasticisers, still, implicit, to some of the flame retarding substances here plasticising effects are additionally attributed:

The **European ENFIRO project**[75] funded by the European Framework Programme compared the flame retardant and application performances as well as hazards and exposure. As for injection moulded products which covers cables and wires, 13 products of alternative flame retarding systems were tested for their mechanical properties and application performance; these 13 products have passed the highest flame retardancy level of UL-94 V-0 that are requirements from the American Underwriters Laboratories (UL) and have been adopted in Europe and Asia as well; the UL-94 requirement is a test for flammability of materials; V-0 is the highest flammability rating.

In 2015, Clariant presented the results of ENFIRO according to different level of concern.[76] The evaluation recommends the metal hydroxide ATH; the phosphorus based flame retardants aluminium diethylphosphinate (Alpi), ammonium polyphosphate (APP) and Dihydrooxaphospha-phenanthrene (DOPO); as the nitrogen based flame retardant melamine polyphosphate (MPP); and finally the synergist zinc (hydroxy)stannate as to see from Figure 8-2.

Figure 8-2: Evaluation of halogen-free flame retardants according to the ENFIRO approach of different level of concerns

Generally safe, few issues of low concern identified	• Aluminium diethylphosphinate (Alpi) • Aluminium hydroxide (ATH) • Ammonium polyphosphate (APP) • Melamine polyphosphate (MPP) • Dihydrooxaphosphaphenanthrene (DOPO) • Zinc stannate (ZS) • Zinc hydroxstannate (ZHS)	• Inorganic and organic substances with low acute (eco-)toxicity and no bioaccumulation potential • Chemical stability required for application results in limited degradation (persistence) • Stannates: in vitro (neuro-)tox effects were not confirmed in-vivo, probably due to low bioavailabillity
Low level of concern for potential environmental and health impact	• Resorcinol bisphosphate (RDP) • Bisphenol-A bisphosphate (BDP)	• RDP toxicity to aquatic organisms is main concern, may be linked to impurities (TPP). Low and high toxicity are found for same test species, which is may be due to batch differences • BDP is persistent
Some issues of concern, risk assessment necessary	• Triphenyl phosphate (TPP) • Nanoclay	• Toxicity of TPP to aquatic organisms is main concern, potential endocrine effects • Nanoclay showed strong in vitro neurotoxicity. May be due to the nanoparticle coating

Source: Clariant (2015)

75 ENFIRO project: Life Cycle Assessment of Environment-Compatible Flame Retardants (Prototypical Case Study); running from 2009-2012, https://cordis.europa.eu/project/rcn/92068_en.html, last viewed 25.09.2018

76 Clariant (2015): SCI Fire and Materials Group, Overview of non-halogen flame retardants; Adrian Beard Clariant Flame Retardants, pinfa.org, 05.11.2015; https://www.soci.org/general-pages/search#q=flame%20retardant%20Beard, last viewed 25.09.2018

As a second, the outcomes of an assessment with the **GreenScreen® for Safer Chemicals**[77] approach are presented in the following. This approach explains itself being *"a method of comparative Chemical Hazard Assessment (CHA) that can be used for identifying chemicals of high concern and safer alternatives."*

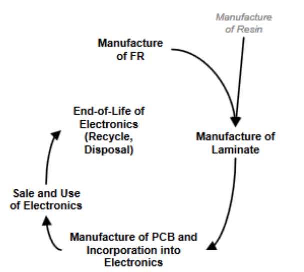
The Green Screen approach was used by the US EPA[78] in order to compare flame retardants in printed circuit boards. The summary of five additively used and halogen-free flame retardants is shown in Table 8-5. Measured data for human health and environmental risk properties (coloured letters in table below) were mainly found to be low (category 2 of 5) or very low (category 1/5); a few times, moderate hazard classification (3 of 5) was derived from empirical data. Once, high hazard could be attributed to human health hazard through repeated doses or silicon dioxide. In terms of the modelled data, the high environmental persistence (category 4 of 5) calculated for all reviewed substances is based on the fact that "substances are comprised of metallic species that will not degrade but may change oxidation stare or undergo complex processes under environmental conditions" (except for melamine polyphosphate). Estimated low and medium hazard for aluminium diethylphosphinate and aluminium hydroxide (categories 2/3 of 5) is "based on analogy to experimental data from a structurally similar compound".

Of those five compounds examined here, melamine polyphosphate is considered to be the less favourable in the over-all perspective.

Table 8-5: Screening Level Hazard Summary for Additive Flame-Retardant Chemicals

VL = Very Low hazard L = Low hazard M = Moderate hazard H = High hazard VH = Very High hazard — Endpoints in colored text (VL, L, M, H, and VH) were assigned based on empirical data. Endpoints in black italics *(VL, L, M, H, and VH)* were assigned using values from predictive models and/or professional judgment.
[R] Recalcitrant: Substance is comprised of metallic species (or metalloids) that will not degrade, but may change oxidation state or undergo complexation processes under environmental conditions. [§] Based on analogy to experimental data for a structurally similar compound. [¤]Concern linked to direct lung effects associated with the inhalation of poorly soluble particles less than 10 microns in diameter. [^] Depending on the grade or purity of amorphous silicon dioxide commercial products, the crystalline form of silicon dioxide may be present. The hazard designations for crystalline silicon dioxide differ from those of amorphous silicon dioxide, as follows: VERY HIGH (experimental) for carcinogenicity; HIGH (experimental) genotoxicity; MODERATE (experimental) for acute toxicity and eye irritation. [¥] Aquatic toxicity: EPA/DfE criteria are based in large part upon water column exposures which may not be adequate for poorly soluble substances such as many flame retardants that may partition to sediment and particulates.

		Human Health Effects											Aquatic Toxicity		Environ-mental Fate		Exposure Considerations
Chemical (for full chemical name and relevant trade names see the individual profiles in Section 4.9)	**CASRN**	**Acute Toxicity**	**Carcinogenicity**	**Genotoxicity**	**Reproductive**	**Developmental**	**Neurological**	**Repeated Dose**	**Skin Sensitization**	**Respiratory Sensitization**	**Eye Irritation**	**Dermal Irritation**	**Acute**	**Chronic**	**Persistence**	**Bioaccumulation**	**Availability of flame retardants throughout the life cycle for reactive and additive flame-retardant chemicals and resins**
Additive Flame-Retardant Chemicals																	
Aluminum Diethylphosphinate[¥]	225789-38-8	L	*L*[§]	L	L	*M*[§]	*M*[§]	*M*[§]	L		L	VL	M	M	*H*[R]	*L*	
Aluminum Hydroxide[¥]	21645-51-2	L	*L*[§]	L	*L*[§]	L	M	*M*[§]	L		VL	VL	L	L	*H*[R]	*L*	
Magnesium Hydroxide[¥]	1309-42-8	L	L	L	L	L	*L*	L	L		M	L	*L*	*L*	*H*[R]	*L*	
Melamine Polyphosphate[1¥]	15541-60-3	L	*M*	*M*	*H*	*M*	*M*	*M*	*L*		L	VL	L	L	*H*	*L*	
Silicon Dioxide (amorphous)	7631-86-9	L[^]	L[^]	L[^]	L	L	*L*[§]	H[¤]	L		L[^]	VL	L	*L*	*H*[R]	*L*	



[1] Hazard designations are based upon the component of the salt with the highest hazard designation, including the corresponding free acid or base.

---

77 https://www.greenscreenchemicals.org/method/full-greenscreen-method, last viewed 25.09.2018

78 US EPA (2015): Flame retardants in printed circuit boards. Final Report, August 2015. United States Environmental Protection Agency (US EPA). Publication 744-R-15-001 under the Design for the Environment programme, available under: https://www.epa.gov/sites/production/files/2015-08/documents/pcb_final_report.pdf

Note: This table contains hazard information for each chemical; evaluation of risk considers both hazard and exposure. Variations in end-of-life processes or degradation and combustion by-products are discussed in the US EPA (2015) report but not addressed directly in the hazard profiles. The caveats listed above must be taken into account when interpreting the information in the table.

Source: US EPA (2015)

8.3. Data basis for alternatives and uncertainties

There is certainty to the point that there is no substitution of MCCPs possible through one substance: As MCCPs perform as secondary plasticizer and as flame retardant, substitution has to be achieved through at least two others substances.

Thus a lot of substitution combinations will be possible that can greatly vary in their health and environmental hazards. Some groups of existing substitutes need further assessment before being used right away, e.g. the tri-substituted organophosphorus esters, such as e.g. tricresyl phosphate. KEMI (2018) additionally states that potential substitutes, e.g. phosphate esters, are not immediately available on the market in the required quantity because they have not been registered under REACH or have been registered only in small tonnages. However, a restriction of a substance under RoHS always includes a transition period that also allows an adaption of production capacities.

Uncertainties concern also the (eco-)toxicological profile of alternative polymer material; no respective information is available. There is evidence for the application of halogen-free polymer material applied on the market given through the industry-based statistics of the European Council of Vinyl Manufacturers.

8.4. Conclusion on alternatives

Alternatives for MCCPs for the plasticising as well as the flame retarding effects are commercially available on the market. A one-fits-all substitution is not probable, rather soft PVC formulation for cable and wire without MCCPs will be reached with a different set of plasticizers and with a varying set of flame retardants.

Addressing direct substitutions of MCCP by one or rather more substances, the following conclusion is drawn based on the former outlined availabilities and their hazard profiles: Some potential alternatives (e.g. ATO, Trixylylphosphate, Triphenylphosphat) have undesirable characteristics in their human health profile; LCCP, the most structurally similar alternative to MCCP, perform better in the human health assessment but raises concern with regards to PBT properties, thus, is unfavourable for the environment.

Preferable options are the metal hydroxide (ATH, MTH), the synergist zinc (hydroxy)stannate as well as some of the phosphorus based flame retardants (case-by-case decision), and finally nitrogen based flame retardants. This conclusion is in line with other assessments.[79]

On the side of the alternative polymer materials, HFFR-LSFOH compounds are a welcomed trend as halogenated flame retardants as well as halogenated polymer material (PVC, PFCs) are avoided. The variety of alternative materials enlarges the possibilities for substitution; these alternative materials and their compatibility with flame retardants were not assessed for their

[79] Op. cit. KEMI (2018); ENFIRO (2009-2012) & Green Screen Assessement by US EPA (2015)

hazardous properties as explained above. But, in these materials, Mg and Al hydroxide are the main flame retarding substances (if no inherently inflammable material is used) which are considered environmentally friendly and without human health hazards.

9. DESCRIPTION OF SOCIO-ECONOMIC IMPACTS

9.1. Approach and assumptions

The socio-economic analysis is based on the comparison of two scenarios.

- The **business-as-usual** scenario, that serves as a baseline for comparison, in which MCCPS are not restricted and can be applied further in EEE to be placed on the EU market.
- The **restriction scenario**, in contrast assumes that MCCPs are added to Annex II of the RoHS Directive, prohibiting their use in EEE once the restriction comes into force.

The analysis focusses on the differences between these two scenarios in terms of expected economic, environmental and social impacts.

For the analysis, it is assumed, that the substitution of MCCPs in PVC cable-insulation does not have an effect on the lifetime of the EEE nor on its usability in its intended use. It is assumed that 15,000 t/a of MCCPs are placed on the market in the EU as part of EEE.

It is furthermore clarified that cables with a rated voltage of more than 250 Volts do not fall under the RoHS 2 Directive and would thus not be affected by a restriction, i.e. differences in impact are not expected for such cables. Impacts related to such cables are therefor not discussed in the following sections.

9.2. Impact on chemicals industry

MCCP manufacturers

KEMI (2018) explains that in the REACH registration data that twelve registrants, three of which are only representatives have compiled and submitted information on MCCPs. As it is not clear from this data how many of the registrants are EU companies and how many represent manufacturers of imported volumes, KEMI assume that there are <12 MCCP manufacturers in the EU. The number of employees of such manufacturers is not known. KEMI further note that four of the registrants of MCCPs have also provided data for the registration of LCCPs, which may be used as a substitute for MCCPs.

Under the restriction scenario, the revenues of chemical manufacturers from MCCP-sales would be lost (aside from MCCP for manufacture of PVC cables with a rated voltage above 250 Volts). Assuming a volume of MCCPs of 15,000 t/a in EEE, and the average market price of 850E/t, KEMI (2018) estimates the value of the affected market to be a maximum of ca. €12.8 million.

On the other side, should MCCPs be phased-out, an increase in sales of possible substitutes would be expected. In this sense, revenues of manufacturers of substitutes, such as LCCPs are expected to increase under the restriction scenario and would compensate at least partially the MCCP-related revenue losses. This would provide a direct set-off of losses for those manufacturers who place both MCCPs and LCCPs on the market (four of the MCCP registrants) and may also lead to a shift in market share from manufacturers who only produce MCCPs (8 registrants) to those producing both (4 registrants) or to manufacturers of other alternatives (see below). The price of LCCPs per tonne is stated by KEMI (2018) to be ca. 24 % higher than MCCPs, or €1050 (LCCPs) vs. €850 (MCCPs) per tonne. In this sense, the shift towards this alternative would be expected to cover the losses of the respectively reduced MCCP production volumes. Aside from LCCPs, there is a wide variety of alternatives that current users of MCCPs could apply, both in terms of alternative substances (and combinations thereof) and alternative materials (i.e. substituting PVC). The benefits for the manufacturers of alternative substances cannot be reliably quantified. However, here too it is to be expected that revenues of increased sales of alternatives would set-off losses of decreased MCCP sales. It is also expected that EU companies would be among the beneficiaries as most of the identified alternative substances have been registered under the REACH Regulation and it is thus expected that at least some of these will be manufactured in the EU.

Manufacturers of PVC and alternative polymers

Under a restriction scenario, PVC manufacturers will have to bear the costs of switching to alternative materials and reformulating the PVC production. In some cases, the formulation of PVC could be changed, using substance alternatives for MCCPs. In such cases, the phase-out would entail an initial investment in the reformulation of PVC for relevant applications. Depending on the cost differences between MCCP and its substance alternatives, losses of PVC based MCCP formulations may be set-off to some degree by PVC based on other additives. KEMI (2018) refer to a publication by Weil et al (2006)[80] explaining "*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*". This would suggest that substance substitutes may lead to the use of higher volumes of other substances in the formulation of PVC, though it is difficult to conclude from this as to the differences in production costs.

In other cases, it can be expected that users will decide to replace PVC with other polymers, eliminating the need for MCCP. In such cases, manufacturers of other polymers would have increased revenues that would also partially set-off the losses related to the MCCP phase-out.

As it can be understood that the volumes of PVC manufacture are decreasing, it can be assumed that in some cases, alternative formulations shall already be available, reducing the initial investment costs in reformulation of PVC or of alternative polymers. In these cases, the difference between the business-as-usual scenario and the restriction scenario shall depend on the differences in volumes of use and costs of the alternative polymers and additives applied. Where the phase-out of MCCPs shall result in higher volumes of use of other substances, it is difficult to say if this shall also result in higher formulation costs, though it is understood that MCCP was commonly used in the past as it was relatively inexpensive and enhanced the qualities of other additives used in PVC.

The distribution of revenue losses and revenue gains between PVC manufacturers and manufacturers of other polymers shall depend on the rout of replacement chosen as well as on whether some of the manufacturers also manufacture alternatives.

[80] Cited by KEMI (2018) as Weil, E. D., Levchik, S., & Moy, P. (2006). Flame and Smoke Retardants in Vinyl Chloride Polymers – Commercial Usage and Current Developments. Journal of Fire Sciences, 24, 211-236.

It is possible that the reduction in demand for MCCPs could affect employment in enterprises manufacturing MCCPs. KEMI (2018) refer to data from VinylPlus from 2016[81] as to five companies representing 70% of the total EU PVC market, which operate 41 production plants located in 21 different sites. These operations have a total of 7,000 employees, though not all of these can be connected to the PVC manufacture nor to PVC containing MCCPs.

In parallel, however, it would also be expected that the increase in demand of MCCP alternatives shall lead to a contra-affect in relation to employment in enterprises manufacturing PVC applying substitutes or alternative polymers. In this sense, it is expected that the total impacts on employment in this respect shall not be high but rather that the distribution of employees between manufacturers of MCCP and its alternatives may change. Though numbers as to such manufacturers were not available, it is assumed that four of the MCCP manufacturers also manufacture LCCPs and for such manufacturers it is assumed that a shift from MCCPs to LCCPs shall compensate losses related with a restriction and thus also possible impacts on employment.

The various impacts cannot be quantified with the information currently available.

9.3. Impact on EEE producers

Three cost elements can be envisaged: the change in the cost of components and EEE through the change in plasticiser/flame retardant cost; the cost of process and equipment adaptations to the chosen alternative; and the cost of re-qualification of the new products.

Cable manufacturers

Cable manufacturers may face increased costs due to the higher market price of alternative plasticisers and flame retardants. For instance, KEMI (2018) refer to information form UK CA (2008) that the use of LCCPs is expected to result in a cost increase of 20-160 % and for the phthalates DINP and DIDP, this cost increase is expected to be in the region of 40-60 %. Phosphate esters have up to four times the cost of MCCPs. Only aluminium hydroxide appears to be less costly than MCCPs. KEMI (2018) estimates the total increased annual cost per year for cable manufacturers at a maximum of € 27 million, when replacing half of the 15,000 tonnes of MCCP with LCCP (accounting for ca. € 1.5 million additional costs) and the other half with a combination of DINP and 2-Ethylhexyl diphenyl phosphate (accounting for ca. € 25.4 million additional costs). It is explained that if a higher share of MCCP would be replaced with LCCP, the total costs would be lower.

The substitution of alternative plastic materials (e.g. polyethylene, polypropylene, fluoroplastics) for PVC is likely to increase production costs by 50-200 %. Consequently, the production of PVC-free electrical insulation is associated with 10-20 % higher costs.

Technically, the cost of process and equipment adaptations might not be significant. Necessary process and equipment adaptation specific to MCCPs and PVC cables are estimated to reach ca. € 1.1 million per year.

The cost of development, re-qualification, and approval of reformulated products cannot be quantified. However, the approval of medium and high voltage cables can take up to two years of

[81] Cited by KEMI (2018) as VinylPlus. (2016). Progress Report 2015. Retrieved from http://www.vinylplus.eu/uploads/Modules/Bannersreport/160826_vinylplus_2016_web_ps_singlepage-version.pdf, the 10 October 2016

testing, indicating that this may be an important parameter to consider in terms of the transition period needed for a restriction.

EEE producers

Estimating the magnitude of costs of EEE manufacturers is difficult. The relevant cost elements include technical costs and compliance costs. KEMI (2018) assumes that cable manufacturers might pass on the costs for research into suitable alternatives for MCCPs to the EEE manufacturers. The part of this additional cost can sum up to be € 28.1 million/a for the first five years and € 27 million/a thereafter, seeing as process and investments in equipment modifications would only be expected in the transition period.

On the basis of domestic production representing 59 % of overall EEE consumption in the EU, KEMI (2018) assumes that the economic burden on EU-based manufacturers of EEE would be at least €16.6 million/a over the first five years and € 16 million/a thereafter, with the rest being borne by non-EU manufacturers of EEE.

Compliance costs are estimated to be marginal, seeing as most manufacturers have already established a system for ensuring compliance with the RoHS Directive (i.e. administrative costs of compliance). In conclusion, the overall cost increase would be very small in comparison to the actual size of the EEE market.

9.4. Impact on EEE users

It can be envisaged that cable manufacturers would aim to pass at least part of their costs to their customers (EEE producers), which in turn may pass them on in the form of increased EEE retail prices. However, the amount per piece of equipment is expected to be very small, seeing as in the total composition, the amount of MCCP used in a EEE product and the respective amounts of substances used for its substitutions have a very small impact in the product price.

KEMI (2018 provide the following calculation to illustrate the range of impact for consumers on the base of a single product:

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

9.5. Impact on waste management

Citing the Recovinyl website[82], KEMI (2018) estimates a total of 52 companies involved in PVC cable waste recycling in the EU. Assuming each of these employs between 5-15 workers, KEMI estimates that 250-780 individuals are involved in PVC recycling in the EU, however, it is not assumed that the restriction scenario would affect the employment of these individuals.

[82] Specified in KEMI (2018) as 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 for impacts on waste management, KEMI (2018 estimate that 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.

9.6. Impact on administration

Based on available information, it can be understood that the common testing methods for MCCPs are cost effective, but not always accurate in detecting and quantifying MCCPs whereas newer and more accurate methods are still expensive (KEMI (2018)).

Under a restriction scenario a burden of additional costs is expected for manufacturers and importers as also for regulators that shall need to determine the presence of MCCPs in PVC cables in order to ensure compliance of EEE. Though for these actors, the performing of such testing would result in additional costs, this expenditure in turn would be directed to testing laboratories, increasing their revenues. In this sense, whether this impact is to be seen as a cost or a benefit depends on the view of the stakeholder. KEMI (2018) refer to an estimation of the Austrian Federal Environment Agency (Umweltbundesamt, 2014) that had assumed 7,000 tests per year to be conducted in the EU. Cost estimations were not available.

9.7. Impact on Human health

KEMI (2018) has summarised estimated impacts on health expected under a restriction scenario. Stakeholder categories related to the use and end-of-life phase (of relevance to the RoHS Article 6(1) criteria) are reproduced in Table 9-1. Details for additional categories can be found in KEMI (2018).

Table 9-1: Summary of human health impacts along the supply chain under the Restriction scenario

Supply chain stakeholder category	Number of EU companies	Number of potentially exposed workers	Impacts on human health	Comments
WEEE treatment installations (shredding)	450	2,250-6,750	Low benefit	Modelling undertaken by KEMI shows a maximum long-term inhalative 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. The risk characterisation has not raised any.
PVC waste recyclers (shredders)	52	250-780	Benefit	Modelling by KEMI shows a maximum long-term inhalative 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. The risk characterisation has raised some concern over inhalation exposure. 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 by KEMI shows a maximum local dermal exposure of workers of 1.2 mg/cm^2 (calendering operations). The risk characterisation has raised some concern over inhalation exposure. Actual risk will depend on RMMs and operating conditions. The EU RAR did not identify an unacceptable risk to workers' health under all PVC-related scenarios examined
Landfills	8,400	Unknown	Unknown	No discernible exposure is expected. An assessment of exposure and risk was not undertaken by KEMI (2018)
Incinerators	715	Unknown	Unknown	No discernible exposure is expected. An assessment of exposure and risk was not undertaken by KEMI (2018)
Consumers/general public	-	500 million citizens	Unknown	An assessment of exposure and risk has not been undertaken by KEMI (2018). The EU RAR established that there was no unacceptable risk for consumers or for humans exposed via the environment

Source: Adopted from KEMI (2018) Table 40

Note: *PVC compounders can be considered part of the manufacturing value chain, however, seeing as they combine recyclate PVC in their processing which is a result of the waste phase (PVC recycling) this category has been included here.

Kemi (2018) summarise that under the restriction scenario, benefits would generally be limited to the shredding of PVC cable waste and the compounding of PVC with MCCP-containing recyclate, though the calculated Risk Characterisation Ratios that give rise to concern are only marginally higher than 1. In absence of an exposure-risk relationship for MCCPs, it is not possible to monetise the benefits arising for workers under the Restriction Scenario. The key beneficiaries are explained to be a group of an estimated max. 2,000 workers in the EU PVC industry.

The consultants cannot follow the last statement seeing as for all stakeholder categories related to PVC manufacture (aside from compounders) impacts are of unknown or uncertain range and seeing as some of the benefits are expected in the waste phase (shredding at WEEE and PVC recycling installations).

Furthermore, in the course of this evaluation, additional risks have been investigated. Information as to elevated dust levels derived from samples taken from private homes are detailed in Section 6.1.3 and suggest that MCCPs emit from articles in which they are contained. Impacts related to these emissions are discussed in Section 7.3. Based on the sample data, at present a risk cannot be determined, however given the current investigation of MCCPs as a vPvB[83] substance and the harmonised classification that MCCPs "May cause harm to breast-fed children", it cannot be ruled out that this shall not change in the future. This has to do both with the assumption that a vPvB classification of MCCPs would result in the determination of stricter DNELs and PNECs for this substance, but also with the general understanding that continued use of a vPvB substance results in its accumulation in the environment, i.e. in this case in households and could increase the risk over time.

9.8. Impact on the environment

KEMI (2018) has summarised estimated impacts on the environment expected under a restriction scenario. Stakeholder categories related to the use and end-of-life phase (of relevance to the RoHS Article 6(1) criteria) are reproduced in Table 9-1. Details for additional categories can be found in KEMI (2018).

[83] See "Brief report from the 22nd PBT EG meeting (Helsinki, 3-4 September 2019), available under: https://echa.europa.eu/documents/10162/21877836/Brief_report_PBTEG22.pdf/647a3dc4-6bcc-e2b7-5d29-c4b0945a0d37, last viewed 20.11.2019

Table 9-2: Summary of human health impacts along the supply chain under the Restriction scenario

Supply chain stakeholder category	Number of EU companies	Impacts on the environment	Comments
WEEE treatment installations (shredding)	450	Benefit	Risk Characterisation Ratios calculated by KEMI (2018) do not show an unacceptable risk with MCCP. However, an estimated 0.75 tonnes of MCCPs are expected to be released to air each year and in this sense a restriction would lead to **a decrease of 0.75 tonnes of MCCP to air**.
PVC waste recyclers (shredders)	52	Benefit	Risk Characterisation Ratios calculated by KEMI (2018) do not show an unacceptable risk. However, an estimated 1.09 tonnes of MCCPs are expected to be released to air each year and in this sense, a restriction would result in **a decrease of 1.09 tonnes of MCCP to air**.
PVC compounders*: PVC formulation	<50	Benefit	Risk Characterisation Ratios calculated by KEMI (2018) show a concern for marine water and sediment. An estimated 0.36 and 0.12 tonnes of MCCPs are expected to be released to air and water respectively each year and in this sense, a restriction would result in **a decrease of 0.36 and 0.12 tonnes of MCCP to air and water**.
PVC Conversion		Benefit	Risk Characterisation Ratios calculated by KEMI (2018) show a concern for freshwater, marine water and sediment. An estimated 0.9 and 0.9 tonnes of MCCPs are expected to be released to air and water respectively each year and in this sense, a restriction would result in **a decrease of 0.09 and 0.09 tonnes of MCCP to air and water**.
Landfills	8,400	Neutral - Benefit	Under normal operating conditions, releases of MCCPs to the environment should be adequately controlled. However, in the opposite situation there might be release of MCCPs to the environment and therefore a benefit.in the form of **a decrease of 0 to 6.2 and 0 to 21.1 tonnes of MCCP to air and water**. (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**	No benefit in the restriction scenario**. Under normal operating conditions, releases of MCCPs to the environment should be adequately controlled. Modelling results suggest that **0.12 tonnes of MCCPs are released to air and 0.06 tonnes are released to water each year**).

Source: Adopted from KEMI (2018) Table 41

Note: *PVC compounders can be considered part of the manufacturing value chain, however, seeing as they combine recyclate PVC in their processing which is a result of the waste phase (PVC recycling) this category has been included here.

** It is not clear why KEMI specify that now benefits are expected in the restriction scenario while also stating that modelling results suggest that releases to air and water occur. Possibly, a benefit would be expected here as well in the form of decreased releases, though this may depend on the performance of the specific incinerator and would thus translate to a neutral-beneficial impact.

KEMI (2018) summarize their results, expecting that 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. A distinction is made in this respect between well operated landfills and incinerators under the strict conditions prescribed by regulation where releases of MCCPs from the PVC matrix should be low and between not well operated landfills and incinerators where possible releases have been calculated and cannot be neglected. The overall releases of MCCPs that would be eliminated are estimated to amount to 4-27 tonnes per year if taking into account emissions from not well operated landfills and incinerators. It is further noted that elimination of releases of MCCPs from these activities would also mean the elimination of releases of SCCPs which are to be found in imported commercial MCCPs products.

Further data provided by the Norwegian Environment Agency (see Section 6.2) shows MCCP levels detected in various biota. Among others, samples were taken from cod liver and blue mussels on a repeated basis in 2012, 2015 and 2016 and suggest that the levels of MCCP in the environment are increasing. This gives more weight to the benefit of reduced emissions concluded for the restriction scenario by KEMI.

Additional findings reported on by Glüge et al. (2018) show relatively high MCCP concentrations found in Arctic fish and so suggest that MCCPs are able to undergo long-range atmospheric transport. Though a level of uncertainty is discussed in relation to these results in Section 6.2.1, seeing that the increased time trends are also reported through the Norwegian data suggests that they are not to be neglected. This would also support the benefit related to emissions prevention that would result from a restriction scenario.

Considering these results against the background of MCCPs being in the process of identification as very persistent and very bio accumulative (vPvB)[84] and in light of their potential for "high chronic toxicity to aquatic invertebrates" suggests that the benefit to the environment of a restriction scenario is to be considered significant. The understanding that a substance is persistent, bio accumulative and may have chronic effects on the environment gives more weight to the benefit of preventing possible releases to the environment in the future.

9.9. Total socio-economic impact

In relation to the differences in impacts between the businesses as usual scenario and the restriction scenario, the possible costs of a restriction are to be compared with its possible benefit.

Though it is expected that the restriction shall result in costs for MCCP manufacturers (up to €12.8 million which is the value of the affected market) possibly also affecting the number of employees of such enterprises, these are expected to be set-off at least to some degree by benefits expected for manufacturers of alternatives and subsequent increases in employment. This is of particular relevance for four manufacturers of MCCPs that are understood to also manufacture the alternative LCCPs.

As for PVC manufacturers, it is unclear to what degree actual costs can be expected here. Though a shift is expected from PVC containing MCCPs to PVC containing alternatives to MCCPs and possibly also towards alternative polymers, a decrease in PVC manufacture is already observed and it is possible that costs related to the need to reformulate and ensure the performance of alternatives have already incurred in the past, at least for some applications, and are thus of a low magnitude. As for costs related to alternative materials, here it can be seen that alternatives are often costlier than MCCPs, however these costs are to be shifted to component (e.g., cables) and EEE producers and subsequently to consumers, meaning that PVC and other polymer manufacturers could see higher total revenues in the restriction scenario.

Regarding manufacturers of related components (e.g., cables) and EEE, KEMI (2018) estimate that the quantifiable costs associated with a restriction on the use of MCCPs accounts for € 28.1 million per year over the first five years and € 27 million/y thereafter. KEMI notes that this sum may not reflect cost elements that could not be monetised such as the cost of re-qualification and re-certification of MCCP-free cables.

It is expected that these costs would be transferred to the consumer, i.e. in the form of an increase in the costs of products in which MCCP containing cables are currently in use. In this respect, KEMI has estimated a cost increase of € 0.003 per kilogram of EEE or less than €1 for a single large appliance sold to the consumer. The consultants regard this difference as an acceptable cost

[84] See footnote 83.

difference, assuming that it would be countered with a positive impact on the environment and/or on health.

The benefits of a substance restriction are related to the decrease in worker exposures to MCCPs along the supply chain as well as to the decrease in emissions to the environment. A decrease in emissions in household dust may also be of relevance in light of the pending classification of MCCPs as a vPvB substance[85].

Based on the estimations of KEMI (2018), under the restriction scenario, worker exposures to MCCPs will be eliminated along the supply chain and a total of at least 4.12 tonnes of MCCPs per year would no longer be released to air and water. Calculating the monetised costs in relation to the amounts of emissions to be prevented per year after the 5th year of the restriction suggests that the cost of eliminating one tonne of MCCP emissions is: *"€27 million ÷ 4.12 tonnes = ca. €6,600 per kilogram of MCCPs released (without discounting)*". Though this gives indication as to the cost of preventing MCCP emissions, it is not to be interpreted as the benefit of the reduction.

It is not straightforward to estimate the benefit of the prevention of MCCP emissions in monetary terms. Nonetheless, the observed increase in the presence of MCCPs in biota contributes to the weight of such benefits, particularly given the pending classification of MCCPs as a vPvB substance.

[85] See footnote 83.

10. RATIONALE FOR INCLUSION OF THE SUBSTANCE IN ANNEX II OF ROHS

MCCPs are a UVCB substance due to their unknown or variable composition that varies in chain length and in degree of chlorination. The harmonised classification of MCCPs of being reprotoxic via lactation of breast-fed children (H362), and of having very high acute and chronic toxic effects to aquatic life (H400), only partly reflects the hazardous potential that is caused by MCCPs:

- MCCPs are suspected of being PBT, and are currently under substance evaluation under REACH: The requested information concern especially the congeners that have a high chlorine content at or above 50 % by weight; these have now been generally recognized for being vPvB in the last PBT meeting of 3-4 September 2019; the assessment however still needs to be finalised.
- Whereas commoditised MCCPs traded in the EU contain less than 1 % of SCCPs (short-chain chlorinated paraffins), commoditised MCCPs available in other world regions (e.g. China) contain higher concentrations of SCCP. SCCPs have been recognized as being a POP substance.

To conclude, MCCPs manufactured predominantly in Europe contain congeners that are very likely vPvB, or MCCPs manufactured in Asia contain SCCP. This means that no risk assessment is applicable since a safe concentration cannot be established with sufficient reliability, because the substance does not degrade and furthermore even accumulates in biota. Thus, as regards a classical risk assessment applying e.g. to the environment, a ratio of PEC/PNEC is not sufficient for assessing the risk.

The function of MCCPs is described as being a secondary plasticiser (extender) with flame retardant properties; the use in PVC and in rubber products, in particular electric cables, is confirmed. For the quantities of MCCPs, no actual data have been provided by stakeholders. It can, however, reliably be assumed that MCCPs are used in relevant quantities in EEE mostly as constituents of PVC insulations for electric cables, wires and other soft plastic or rubber components, including polyurethane, polysulphide, acrylic and butyl sealants.

The risk evaluation is summarized as follows:

- Risks for workers: The MCCPs' application areas are likely to result in MCCP releases during recycling and disposal treatment of waste electric and electronic products (WEEE): A release of MCCPs in the form of vapours and dust can typically occur when shredding PVC cable waste and other WEEE. Other release routes are formulation, conversion, and re-use of PVC recyclate as well as final disposal. The processing of such recycling materials subsequently entails inhalative exposure of workers.
- Risks to the environment: The release of MCCPs from WEEE waste management has to be emphasized: This risk has been determined at present only by considering the current PNECs, which are in view of the vPvB properties a severe underestimation of the risk. In other words, though a risk is already apparent, it is possible that the actual risk is more severe, given the potential of being a vPvB substance.

  Environmental exposure has manifested in precipitation in soil and aquatic sediments, where secondary poisoning of organisms is likely to occur following uptake of MCCPs into the food chain. Unacceptable risks to human health and the environment have in particular been identified for treatment and final disposal of WEEE, but also in reformulation and use of recycled

PVC. Given the widespread use of PVC insulated cables, the implementation of adequate risk management measures cannot be guaranteed in all possible points of release.

- Risks for consumers: There are studies detecting MCCPs in house dust. Applying the current DNELs, no risk for consumers can be determined. However, taking into account the draft conclusion of the PBT expert group on the vPvB properties, it is likely that this conclusion is an underestimation.

The socio-economic analysis points to costs to be transferred to the consumer in a range that are perceived to be acceptable in light of the expected benefit in the form of elimination of exposure risks for workers and for the environment (prevention of emissions and subsequently risks to biota).

The restriction proposal by KEMI (2018) is supported by this assessment. KEMI (2018) proposes 0.1 % by weight as a maximum tolerable MCCP concentration in homogenous EEE material. Regarding the global differences to the nomenclature and CAS numbers used in various regions, a restriction of chlorinated paraffins should rather use a definition of chlorine content in relation to a chain length within a certain range instead of referencing to CAS numbers. It is therefore recommended to restrict MCCPs and add an explanation that this entry covers chlorinated paraffins containing paraffins with a chain length of C14-17 – linear or branched.

11. List of References

Amoyaw-Osei, Y.; Agyekum, O. O.; Pwamang, J. A.; Mueller, E.; Fasko, R.; Schluep, M. (2011): Ghana e-Waste Country Assessmen. Accra. Online verfügbar unter http://ewasteguide.info/files/Amoyaw-Osei_2011_GreenAd-Empa.pdf, last viewed: 10.12.2015

Anixter (2012): LOW SMOKE ZERO HALOGEN WIRE AND CABLE BEST PRACTICES https://www.anixter.com/content/dam/Anixter/White%20Papers/12F0003X00-Anixter-LSZH-WP-W%26C-EN-US.pdf (assessed 21.11.2019)

Apple (2016): Apple Regulated Substances Specification 069-0135-J; https://www.apple.com/supplier-responsibility/pdf/Apple-Regulated-Substance-Specification.pdf, last viewed 24.07.2018

Atiemo, S.; Faabeluon, L.; Manhart, A.; Nyaaba, L.; Schleicher, T. (2016): Baseline Assessment on E-waste Management in Ghana. Accra.

Buchert, M.; Manhart, A.; Mehlhart, G.; Degreif, S.; Bleher, D.; Schleicher, T. et al. (2016): Transition to sound recycling of e-waste and car waste in developing countries - Lessons learned from implementing the Best-of-two-Worlds concept in Ghana and Egypt. Freiburg. Online available at https://www.oeko.de/oekodoc/2533/2016-060-en.pdf, last viewed: 17.07.2018.

"Cavallero, A. (2017): About PVC stabilisers and Sustainability, Dr. Alain Cavallero, European Stabiliser Producers Association, ESPA; 1st PVC4CABLES conference, 26 October 2017; https://www.pvc4cables.org/images/Cavallero.pdf, last viewed 25.09.2018

Chen, H. et al. (2018): Combined Effects of Dust and Dietary Exposure of Occupational Workers and Local Residents to Short- and Medium-Chain Chlorinated Paraffins in a Mega E-Waste Recycling Indsutrial Oark in South China; Environmental Science and Technology 2018, 52, 11510-11519.

Clariant (2015): SCI Fire and Materials Group, Overview of non-halogen flame retardants; Adrian Beard Clariant Flame Retardants, pinfa.org, 05.11.2015; https://www.soci.org/general-pages/search#q=flame%20retardant%20Beard, last viewed 25.09.2018

Coelhan, M., Hilger, B. (2014): Chlorinated Paraffins in Indoor Dust Samples: A Review; Current Organic Chemistry 2014, 18, 2209- 2217.

DE MSCA (2016): Justification Document for the Selection of a CoRAP Substance; https://echa.europa.eu/documents/10162/44adc62e-ff48-4ce8-9c4f-58dd8b77253a, last viewed 25.09.2018

Dell (2018): Specification Materials Restricted for Use Revision: A03-00, Document Number: ENV0424; https://www.dell.com/learn/us/en/05/shared-content~solutions~en/documents~env0424-a02.pdf, last viewed at 24.07.2018

ECHA (2014): Decision on Substance Evaluation for tris(2-ethylhexyl)benzene-1,2,4-tricarboxylate; https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e4cae, last viewed 25.09.2018

ECHA (2014): Decision on Substance Evaluation Pursuant to Article 46(1) of Regulation (EC) No 1907/2006 for alkanes , C14-17, chloro (MCCP, Medium-chain chlorinated paraffins); CAS No 85535-85-9 (EC No 287-477-0); case no. A-004-2014; https://echa.europa.eu/about-us/who-we-are/board-of-appeal/decisions, last viewed 19.04.2018

ECHA (2016): Decisions on Substance Evaluation for Tris(methylphenyl) phosphate; see the different decisions for all Registrant(s) and separate decisions to individual Registrants at https://echa.europa.eu/de/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e180694747, last viewed 25.09.2018

ECHA (2016): Decisions on Substance Evaluation for Trixylyl Phosphate; https://echa.europa.eu/documents/10162/94e8d9c9-be37-6349-92ba-dddfac4122b5, last viewed 25.09.2018

ECHA CL Inventory: Entry for Alkanes, C14-17, chloro (20189); https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/94445, last viewed 24.07.201811.11.2019

ECHA: http://www.echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table?search_criteria=85535-85-9, last viewed 15.10.2019

ECHA: http://www.echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table?search_criteria=85535-85-9, last viewed 15.10.2019

ECHA: https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling, last viewed 19.04.2018

ENFIRO project: Life Cycle Assessment of Environment-Compatible Flame Retardants (Prototypical Case Study); running from 2009-2012, https://cordis.europa.eu/project/rcn/92068_en.html, last viewed 25.09.2018

EuroChlor (2018): Euro Chlor views on the proposal to add medium chain chlorinated paraffin (MCCP) to Annex II of the Restriction of Hazardous Substances Directive; Position Paper, July 2018.

EuropaCable (2018a): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_EUROPA_CABLE_MCCP_consultation_1_20180615.pdf, last viewed 24.07.2018

EuropaCable (2018b): Information provided to Questionnaire for Clarification, submitted 09.07.2018

European Centre for Ecotoxicology and Toxicology of Chemicals' Targeted Risk Assessment 3

European Chemicals Agency ECHA (2015): Guidance on Information Requirements and Chemical Safety AssessmentChapterR.15: Consumer exposure estimation; Draft (Public)Version 3.0 October 2015; https://echa.europa.eu/documents/10162/23047722/draft_201510_r15_peg_infreq_uses_en.pdf/4c52b39e-ca5e-4cb2-a6e3-b8020dc8d047, last viewed 20.11.2019

European Commission Environment DG at http://ec.europa.eu/environment/waste/rohs_eee/substances_en.htm, last viewed 24.07.2018.

European Union Risk Assessment Report EU RAR (2005): Alkanes, C14-17, chloro (MCCP) - Part I – environment, Luxembourg: European Commission; https://echa.europa.eu/documents/10162/ad6eebf1-49b2-4a7b-9f73-a2c11109ff0c, last viewed 24.07.2018

European Union Risk Assessment Report EU RAR (2008): Alkanes, C14-17, chloro (MCCP) - Part II Human Health, European Commission, Joint Research Centre, Institute for Health and Consumer Protection; http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/15069/1/lbna24589enn.pdf, last viewed 24.07.2018

European Union System for the Evaluation of Substances

Eurostat (2019): Waste statistics -electrical and electronic equipment. https://ec.europa.eu/eurostat/statistics-explained/pdfscache/32212.pdf. last viewed: 12.11.2019

Finnish Safety and Chemicals Agency (Tukes), Finland (2013): Justification for the selection of a candidate CoRAP substance: bis(2-ethylhexyl) adipate; https://echa.europa.eu/documents/10162/ce16ad6d-513c-4aba-95c3-94276cecc2d2, last viewed 25.09.2018

Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018): Assessment of TBBP-A (tetrabromopisphenol-A) according to the "Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex III) under the RoHS2 Directive". Update August 2018. Fraunhofer ITEM, Fraunhofer IPA, Stuttgart.

Glüge, J., Schinkel, L. et al (2018): Environmental risks of medium-chain chlorinated paraffins (MCCPs) - A review. Environ. Sci. Technol. (52):12, pp 6743-6760

Glüge, J., Schinkel, L., Hungerbühler, K., Cariou, R., Bogdal, C. (2018): Environmental risks of medium-chain chlorinated paraffins (MCCPs) - A review. Environ. Sci. Technol. (52):12, pp 6743-6760

Helsinki Commission, Baltic Marine Environment Protection Commission (2009): Hazardous substances of specific concern to the Baltic Sea, Final report of the HAZARDOUS project; Baltic Sea Environment Proceedings No. 119; http://www.helcom.fi/Lists/Publications/BSEP119.pdf, last viewed

http://chm.pops.int/Implementation/Alternatives/AlternativestoPOPs/ChemicalslistedinAnnexA/Shortchainchlorinatedparaffins(SCCPs)/tabid/5986/Default.aspx, last viewed 24.07.2018

http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#report3: MCCPs are assigned endocrine disruption Cat. 1. This implies that at least one in-vivo study provides clear evidence for endocrine disruption in an intact organism

https://pdfs.semanticscholar.org/41b2/847fe723787a863568f1376aa840042fc8b6.pdf (accessed on 11.11.2019)

https://pdfs.semanticscholar.org/41b2/847fe723787a863568f1376aa840042fc8b6.pdf (accessed on 11.11.2019)

https://www.greenscreenchemicals.org/method/full-greenscreen-method, last viewed 25.09.2018

https://www.hamos.com/products/electrostatic-separators/metal_plastic-separators,35,eng,48, last viewed 25.09.2018

https://www.polyone.com/files/resources//EM_LSFOH_BU_Overview___75360.pdf (assessed 21.11.2019)

https://www.sustainable-recycling.org/

Huisman, J.; Botezatu, I.; Herreras, L.; Liddane, M.; Hintsa, J.; Di Luda Cortemiglia, V. et al. (2015): Countering WEEE Illegal Trade (CWIT) Summary Report, Market Assessment, Legal Analysis, Crime Analysis and Recommendations Roadmap. Lyon. Online verfügbar unter http://www.cwitproject.eu/wp-content/uploads/2015/09/CWIT-Final-Report.pdf, last viewed: 17.07.2018.

INEOS ChlorVinyls (2014): Contribution submitted 24.03.2014 during stakeholder consultation; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140324_INEOS_Contribution_RoHS_SC_Substance_Review_MCCP.pdf, last viewed 19.04.2018

International Chemical Secretariat (CHEMSEC): http://chemsec.org/business-tool/sin-list/about-the-sin-list/, last viewed 24.07.2018

International Chemical Secretariat (CHEMSEC): http://sinlist.chemsec.org/search/search?query=63449-39-8, last viewed 24.07.2018

International Chemical Secretariat (CHEMSEC): http://sinlist.chemsec.org/search/search?query=SCCP, last viewed 24.07.2018

JRC-IHCP, 2011 is the European Union Risk Assessment Report EU RAR (2011): Part II Human Health. ALKANES, C14-17, CHLORO (Medium-Chained Chlorinated Paraffins). Joint Research Centre Institute for Health and Consumer Protection. JRC-IHCP; http://publications.jrc.ec.europa.eu/repository/bitstream/JRC66049/lbna25202enn.pdf, last viewed 24.07.2018

Koehnlechner, R.: Presentation on New separation technologies for plastics; Hamos GmbH, Penzberg/Germany

Manhart, A.; Osibanjo, O.; Aderinto, A.; Prakash, S. (2011): Informal e-waste management in Lagos, Nigeria - socio-economic impacts and feasibility of international recycling co-operations. Final report of component 3 of the UNEP SBC E-waste Africa Project. Lagos & Freiburg.

Norwegian Environment Agency (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Norwegian_Environment_Agency_TBBPA_MCCPS_20180614.pdf, last viewed 24.07.2018

Odeyingbo, O.; Nnorom, I.; Deubzer, O. (2017): Person in the Port Project - Assessing Import of Used Electrical and Electronic Equipment into Nigeria. Bonn. Online available at http://collections.unu.edu/eserv/UNU:6349/PiP_Report.pdf, last viewed: 17.07.2018.

Oeko-Institute (2008): Study on Hazardous Substances in Electrical and Electronic Equipment, not Regulated by the RoHS Directive

Oomen, A.G.; Janssen, P.J.C.M.; Dusseldorp, A.; Noorlander, C.W. (2008): Exposure to chemicals via house dust; https://www.rivm.nl/bibliotheek/rapporten/609021064.html

Pinfa (Phosphorus, Inorganic and Nitrogren Flame Retardants Association) (2017): Flame retardants in electric and electronic applications, non-halogenated phosphorus, inorganic and nitrogen (PIN) flame retardants; October 2017, 3rd edition; https://www.pinfa.eu/wp-content/uploads/2018/05/PINFA_EE_brochure_Edition_2017-11.pdf, last viewed 24.07.2018.

Prakash, S.; Manhart, A. (2010): Socio-economic assessment and feasibility study on sustainable e-waste management in Ghana. Oeko-Institut e.V. Freiburg. Online available at http://www.oeko.de/oekodoc/1057/2010-105-en.pdf, last viewed: 12.11.2015.

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH).

Swedish Chemicals Agency KEMI (2017): Study of a possible restriction of MCCP in electrical and electronic equipment regulated under RoHS, PM 2/17, May 2017; https://www.kemi.se/global/pm/2017/pm-2-17-study-of-a-possible-restriction-of-mccp-in-electrical-and-electronic-equipment-regulated-under-rohs.pdf, last viewed 19.04.2018

Swedish Chemicals Agency KEMI (2018): ROHS Annex II Dossier MCCP, Proposal for a restriction of a substance in electrical and electronic equipment under RoHS; https://www.kemi.se/global/rapporter/2018/report-4-18-rohs-annex-ii-dossier-mccp.pdf, last viewed 24.07.2018

UK CA (2013): Justification for the selection of a candidate CoRAP substance; https://echa.europa.eu/documents/10162/47fa7ee3-8323-4532-bb52-f1d8fe3b5ea4, last viewed 25.09.2018

US EPA (2015): Flame retardants in printed circuit boards. Final Report, August 2015. United States Environmental Protection Agency (US EPA). Publication 744-R-15-001 under the Design for the Environment programme, available under: https://www.epa.gov/sites/production/files/2015-08/documents/pcb_final_report.pdf

VinylPlus, available at https://vinylplus.eu/uploads/Modules/Bannersreport/vinylplus-progress-report-2017.pdf , accessed on 30 July 2018.

Wong, F., Suzuki, G., Michinaka, C., Yuan, B., Takigami, H., de Wit, C.A. (2017): Dioxin-like activities, halogenated flame retardants, organophosphate esters and chlorinated paraffins in dust from Australia, the United Kingdom, Canada, Sweden and China, Chemosphere, 168,(1248).

WSP Environmental Sverige (2018): Indoor Pollutants In Dust From NonHazCity Pilot Families In Stockholm, Test Report On Dust Campaign, Report from Work in GoA 5.4 ”Test your environment”.

12. Appendix I: Contribution to stakeholder consultation hold from 20 April 2018 to 15 June 2018

The following non-confidential contributions were submitted during the 1st stakeholder consultation (see also: http://rohs.exemptions.oeko.info/index.php?id=293):

> Contribution of the **Swedish Chemicals Agency (KEMI)** submitted on 11.06.2018:

>> Proposal for restriction of MCCP under RoHS submitted to the European Commission on 11.06.2018: PDF

>> Assessment of the risk reduction potential of hazardous substances in electrical and electronic equipment on the EU market: PDF

> Contribution of the **Norwegian Environment Agency** submitted on 14.06.2018: PDF

> Contribution of **MedTech Europe** submitted on 15.06.2018: PDF

> Contribution of the **Test and Measurement Coalition (TMC)** submitted on 15.06.2018: PDF

> Contribution of the **Association of Equipment Manufacturers (AEM)** submitted on 15.06.2018: PDF

> Contribution of **Europacable** submitted on 15.06.2018:

>> Part 1: PDF

>> Part 2: PDF

> Contribution of the **Japanese electric and electronic (E&E) industrial associations** submitted on 14.06.2018:

>> Part 1: PDF

>> Part 2: PDF

> Contribution of the **AeroSpace and Defence Industries Association of Europe (ASD)** submitted on 14.06.2018: PDF