Danish Ministry of the Environment
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Survey of short-chain and medium-chain chlorinated paraffins

Part of the LOUS-review

Consultation draft

Title:

Survey of short-chain and medium-chain chlorinated paraffins

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Foreword

Background and objectives
The Danish Environmental Protection Agency's List of Undesirable Substances (LOUS) is intended as a guide for enterprises. It indicates substances of concern whose use should be reduced or eliminated completely. The first list was published in 1998 and updated versions have been published in 2000, 2004 and 2009. The latest version, LOUS 2009 (Danish EPA, 2011) includes 40 chemical substances and groups of substances which have been documented as dangerous or which have been identified as problematic using computer models. For inclusion in the list, substances must fulfil several specific criteria. Besides the risk of leading to serious and long-term adverse effects on health or the environment, only substances which are used in an industrial context in large quantities in Denmark, i.e. over 100 tonnes per year, are included in the list.

Over the period 2012-2015, all 40 substances and substance groups on the LOUS will be surveyed. The surveys include collection of available information on the use and occurrence of the substances, internationally and in Denmark, as well as information on environmental and health effects, alternatives to the substances, existing regulations, monitoring and exposure, and on-going activities under REACH, among others.

On the basis of the surveys, the Danish EPA will assess the need for any further information, regulation, substitution/phase out, classification and labelling, improved waste management or increased dissemination of information.

This survey concerns short-chain and medium-chain chlorinated paraffins (SCCPs and MCCPs). These substances were included in the first LOUS in 1999. The first LOUS also included the long-chain chlorinated paraffins (LPPCs) which were later removed from the list.

The entry in the most recent LOUS for these substances is (Danish EPA, 2011):

- chloroalkanes, C10-13 (short-chain chlorinated paraffins), SCCPs and
- chloroalkanes, C14-17(medium-chain chlorinated paraffins), MCCPs.

The main reason for the inclusion of SCCPs in LOUS is that the substances are classified as carcinogenic and the SCCPs are assessed as PBT substances. The reason for inclusion of MCCPs is that the substances have suspected PBT properties. Furthermore, the reason for inclusion is that SCCPs and MCCPs are on the EU 'Priority list of substances for further evaluation of their role in endocrine disruption'.

The main objective of this study is, as mentioned, to provide background for the Danish EPA's consideration regarding the need for further risk management measures.

The process
The survey has been undertaken by COWI A/S (Denmark) in cooperation with Technological Institutes (Denmark) and Building Research Establishment (U.K.) from October 2013 to May 2014. The work has been followed by an advisory group consisting of:

- Louise Grave-Larsen, Danish EPA, Chemicals
- Thilde Fruergaard, Danish EPA, Waste

- Birgitte Marcussen, The Danish Society for Nature Conservation
- Nikolai Nilsen, Confederation of Danish Industry
- Anette Ravn Bharathan, Danish Working Environment Authority
- Carsten Lassen, COWI A/S

Data collection
The survey and review is based on the available literature on the substances, information from databases and direct inquiries to trade organisations and key market actors.

The literature search included the following data sources:

- Legislation in force from Retsinformation (Danish legal information database) and EUR-Lex (EU legislation database);
- Ongoing regulatory activities under REACH and intentions listed on ECHA's website (incl. Registry of Intentions and Community Rolling Action Plan);
- Relevant documents regarding International agreements from HELCOM, OSPAR, the Stockholm Convention, the PIC Convention, and the Basel Convention;
- Data on harmonised classification (CLP) and self-classification from the C&L inventory database on ECHAs website;
- Pre-registered and registered substances from ECHA's website;
- Data on ecolabels from the Danish ecolabel secretariat (Nordic Swan and EU Flower);
- Production and external trade statistics from Eurostat's databases (Prodcom and Comext);
- Export of dangerous substances from the Edexim database;
- Data on production, import and export of substances in mixtures from the Danish Product Register (confidential data, not searched via the Internet);
- Date on production, import and export of substances from the Nordic Product Registers as registered in the SPIN database;
- Information from Circa on risk management options (confidential, for internal use only, not searched via the Internet);
- Monitoring data from the National Centre for Environment and Energy (DCE), the Geological Survey for Denmark and Greenland (GEUS), the Danish Veterinary and Food Administration, and the European Food Safety Authority (EFSA);
- Waste statistics from the Danish EPA;
- Chemical information from the ICIS database;
- Reports, memorandums, etc. from the Danish EPA and other authorities in Denmark;
- Reports published at the websites of:
  - The Nordic Council of Ministers, ECHA, the EU Commission, OECD, IARC, IPCS, WHO, OSPAR, HELCOM, and the Basel Convention;
  - Environmental authorities in Norway (Klif), Sweden (KemI and Naturvårsverket), Germany (UBA), UK (DEFRA and Environment Agency), the Netherlands (VROM, RIVM), Austria (UBA). Information from other EU Member States was retrieved if quoted in identified literature;
  - US EPA, Agency for Toxic Substances and Disease Registry (USA) and Environment Canada;
  - PubMed and Toxnet databases for identification of relevant scientific literature.

Direct enquiries were also sent to Danish and European trade organisations and a few key market actors in Denmark.

Conclusion and summary

Over the period 2012-2015, all 40 substances and substance groups on the Danish Environmental Protection Agency's List of Undesirable Substances (LOUS) will be subject to survey and review. On the basis of the results, the Danish EPA will assess the need for any further regulation: substitution/phase out, classification and labelling, improved waste management or increased dissemination of information.

This survey concerns short-chain and medium-chain chlorinated paraffins (SCCPs and MCCPs). These substances were included in the first LOUS in 1999. The first LOUS also included the long-chain chlorinated paraffins (LPPCs) which have later been removed from the list.

The substance groups
Chlorinated paraffins consist of a carbon chain with a varying number of chlorine atoms attached to the chain. Commercial products usually are mixtures of different carbon chain lengths and varying degrees of chlorination, and furthermore they consist of a complex mixture of isomers and congeners (substances with the same length and degree of chlorination, but with the chlorine atoms placed in different positions in the molecules). These characteristics complicate the assessments of toxicity and environmental fate of the substances.

By convention, the chlorinated paraffins (CPs) are grouped according to chain length:

- Short-chain chlorinated paraffins (SCCPs) with 10-13 carbon atoms (C10-13);
- Medium-chain chlorinated paraffins (MCCPs) with 14-17 carbon atoms (C14-17);
- Long-chain chlorinated paraffins (LCCPs) with more than 18 carbon atoms.

Most commercial chlorinated paraffin products are liquid and range from relatively low to extremely high viscosity. Chlorinated paraffins are relatively inert substances, which are resistant to chemical attack and are hydrolytically stable (low solubility in water).

The function of the substances depends on the application. In plastics (mainly PVC), rubbers, paint and sealants, they act as plasticisers with flame retardant properties. The flame retardant properties are of importance for some of the applications (e.g. rubber articles for mining and PVC in cables), whereas in other applications, it is only the function as plasticisers which is employed. In metal cutting fluids, the chlorinated paraffins act as lubricants which prevent sliding metal surfaces from seizing under conditions of extreme pressure. The advantages of the chlorinated paraffins are their chemical and physical stability. In leather production, chlorinated paraffins are used in leather liqueurs to provide water repellence, light-fastness and a dry surface feel.

Regulatory framework
SCCPs - Production, placing on the market and use of SCCPs has been prohibited by the POP Regulation (Regulation (EC) 850/2004) in the EU since 2012. Besides a general exemption for substances and mixtures (but not for articles) with a concentration below 1% SCCPs, the Regulation includes two exemptions: Use as fire retardants in dam sealants and as fire retardants in rubber used in conveyor belts in the mining industry.

SCCPs are included in Annex 1 to the POP Protocol to the UNECE Convention on Long-Range Transboundary Air Pollution (CLRTAP). The POP Protocol addresses SCCPs with a degree of chlorination of more than 48% by weight, whereas the POP Regulation addresses all SCCPs regardless of chlorination degree. Neither SCCPs nor MCCPs are addressed by the Stockholm Convention. However, SCCPs have been proposed by the EU for listing under the Convention and are under review by the POPs Review Committee.

SCCPs are furthermore addressed by the CLP Regulation (classified as carcinogenic and toxic in the aquatic environment), Danish and EU emission and environmental monitoring legislation, as well as Danish and EU occupational health legislation.

The Nordic ecolabelling criteria for a range of products restrict SCCPs and other chlorinated paraffins in ecolabelled products. The EU Ecolabelling criteria do not explicitly address SCCPs, but the substances are excluded from some ecolabelled products due to their classification as carcinogenic.

MCCPs – Contrary to the SCCPs, the use of MCCPs is not restricted. MCCPs are not mentioned explicitly in any EU legislation addressing chemicals in products, emissions or wastes. In the CLP regulation, only the most frequently used MCCPs (CAS no. 85535-85-9) have a harmonised classification (toxic in the aquatic environment and adverse effects on or via lactation). Although not specifically mentioned, the MCCPs are addressed by various instruments. MCCPs are the EU Directive on protection of the health and safety of workers from the risks related to chemical agents at work and the corresponding Danish Executive Order.

MCCPs are listed in the Community Rolling Action Plan (CORAP) under REACH by the U.K; the substance evaluation under REACH is ongoing.

Both SCCPs and MCCPs are included in HELCOM's list of priority hazardous substances.

The general prohibition of chlorinated paraffins in the Nordic Ecolabel criteria includes MCCPs. MCCP are not mentioned directly in any of the EU ecolabelling criteria and might therefore be excluded from use only in some ecolabelled articles because of their classification as toxic to the environment.

Manufacture and consumption in the EU

SCCPs - The total registered manufacture and import of SCCPs is indicated to be within the tonnage band 1,000-10,000 t/y. According to the most recent survey from 2009, the consumption for applications now exempt from the general restriction would be no more than 400 t/y and probably less. Updated consumption figures for the two exempt applications have not been obtained.

As mentioned, the EU restriction of SCCPs has an exemption for substances and mixtures with <1% SCCPs. In mixtures such as paint, sealants and adhesives, SCCPs have typically been used as a plasticisers and flame retardants in concentrations well above 1%, and it would not be expected that mixtures with an intentional content of SCCPs below 1% would be produced or imported.

SCCPs may be present in commercial MCCPs in concentrations up to 1%, and the total unintentional content of SCCPs in articles and mixtures with MCCPs may be up to 0.3% (if the mixture or article contains 30% MCCPs).

MCCPs - The total registered manufacture and import of MCCPs is indicated to be within the tonnage band 10,000-100,000 t/y. The total EU production of chlorinated paraffins is approximately 45,000 t/y and, of this, the majority is considered to be MCCPs. The principal uses of MCCPs in 2006 was as plasticiser/flame retardant in PVC (54% of total), in paints/coatings, adhesives and sealants (18%), in rubber and other polymers (11%), as lubricant in metal working/cutting fluids (16%) and in leather fat liqueurs (1%).

The total consumption remained stable from 1994 to 2006, as a decline in the consumption of PVC was counterbalanced by an increase in the consumption of metalworking fluids, paints/coatings, adhesives and sealants and additives for rubber/polymers. The downward trend in the consumption of PVC happens simultaneously with a trend, where the phthalates DINP, DIDP and DPHP gradually have substituted for the phthalate DEHP as the primary plasticiser in PVC. The MCCPs are generally used in higher concentrations in PVC where DEHP is the primary plasticiser.

Manufacture and consumption in Denmark
Chlorinated paraffins are not manufactured in Denmark.

SCCPs – SCCPs are not used for exempt applications in Denmark. SCCPs are not expected to be imported in mixtures and articles intentionally containing SCCPs. SCCPs may be present as an impurity in articles and mixtures containing MCCPs in concentrations up 0.3%.

MCCPs – The total quantities of MCCPs in mixtures registered in the Danish Product Register in 2012 was 68 tonnes, and the main use categories were metalworking fluids, filling and padding materials and other uses which include primers and lubricants. No data are available on the possible use of MCCPs in the production of PVC in Denmark.

The majority of the MCCPs in mixtures and articles sold in Denmark may be imported. In an assessment of MCCPs in articles imported to Norway in 2009, the total import of MCCPs in articles was estimated at 205-409 t/y; of this, 130-280 t/y MCCPs was imported in articles of PVC and 34-101 t/y in articles of rubber. The figures for Denmark are probably quite similar although the import in rubber may be lower (as no underground mining activities take place in Denmark).

Waste management
SCCPs – Waste with more than 1.0% SCCPs shall be managed as hazardous waste according to the Danish statutory order on waste. Materials with an intentional content of SCCPs would typically contain more than one percent of the substance and shall consequently be managed as hazardous waste when they are disposed of. Even though the use of SCCPs is now restricted, materials with SCCPs have been accumulated in society and may be disposed of as waste over the coming years. The main SCCP-containing materials accumulated in society and present in the waste stream are expected to be rubber, sealants and adhesives (e.g. in double-glazed windows), paints and textiles.

Only limited information on the actual presence of SCCPs in building materials in Denmark is available. Some experience has been built up in recent years by Danish laboratories, which sometimes analyse for SCCPs together with the analyses for PCBs, but the data has not been compiled and summarised. Data received from one laboratory shows that a significant portion of the material samples from buildings from the period 1950-1977 (the PCB-period) contain SCCPs above the detection level.

It is anticipated that some construction and demolition waste containing SCCPs (paint and sealant) may be used for material recovery and it cannot be ruled out that these may cause an impact on the environment.

MCCPs - In Denmark, no limit values are established in the statutory order on waste, for waste containing substances classified as toxic to the environment, but the property "ecotoxic" is among the properties which may render waste hazardous. It is, therefore, the responsibility of the municipalities, on the basis of a risk assessment, to define if and when waste containing MCCPs should be managed as hazardous waste. The total quantity of MCCPs in the waste may be up to 500 t/y; i.e. an estimated five times higher than the quantities of SCCPs in the waste. The main waste categories are articles containing PVC (including cables), rubber products, paints/coatings, adhesives and sealants.

The majority of the waste is estimated to be incinerated in municipal solid waste incinerators or landfilled in larger articles of PVC (as they are only present in flexible PVC which is currently not recycled in Denmark). Both SCCPs and MCCPs are nearly 100% destroyed by the incineration process and are not expected to act as precursors for the formation of dioxins and furans. A major product of combustion is hydrogen chloride. As with any other chlorine-containing substances and materials, they may act as chlorine donors for post-combustion *de-novo* synthesis of dioxins and furans in the incinerators, but Danish incinerators have equipment for prevention of formation and releases of dioxins and furan.

Norwegian legislation - The Norwegian Environmental Authorities request separate collection of the double-glazed windows containing SCCPs and MCCPs in conjunction with the collection scheme for PCB-containing windows (Ruteretur). Furthermore, in accordance with the Norwegian legislation, SCCPs and MCCPs are included in the obligatory surveys of hazardous substances by renovation and demolition of buildings, and the quantities of CP-containing waste are reported separately in the national waste statistics.

Waste water and sewage sludge - Very limited data are available regarding SCCPs and MCCPs in Danish municipal sewage treatment plants. In analyses from two municipal sewage treatment plants, the SCCP concentration was below the detection limit, while the MCCP concentration ranged from 500 to 810 ng/l. Analyses of chlorinated paraffins in sewage sludge in Denmark have not been identified. Median levels of MCCPs reported in 2008 in Norwegian sewage sludge ranged between 0.4 and 5.7 mg/kg, with a maximum of 11.8 mg/kg, indicating a decreasing tendency compared to the previous years. In the Norwegian assessment the data suggest little or no risk to various environmental compartments from the levels determined when compared to relevant toxicity data.

Environmental effects and fate

Both SCCPs and MCCPs are multi-constituent mixtures with variable and often unknown composition, and relatively low water solubilities and high log Kow values. This means that the interpretation of much of the environmental fate and effects data is complicated, and that the properties will vary with carbon chain length and chlorine content.

Aquatic invertebrates (in particular *Daphnia magna*) appear to be a sensitive group in terms of aquatic toxicity of both SCCPs and MCCPs. The long-term NOEC for *Daphnia magna* has been determined as 0.005 mg/l for SCCPs and 0.010 mg/l for MCCPs. Toxicity to sediment-dwelling organisms has also been demonstrated for MCCPs (no data are available for SCCPs) and both SCCPs and MCCPs have been shown to cause effects in soil organisms, but only at concentrations of the order of hundreds to thousands of mg/kg dry weight. Combined effects resulting from simultaneous exposure of organisms to both SCCPs and MCCPs are predicted to occur.

SCCPs and MCCPs are expected to be degraded in the atmosphere by reaction with hydroxyl radicals (half-life 1.9-7.2 days for SCCPs and 1-2 days for MCCPs). Both SCCPs and MCCPs have the potential for long-range transport via the atmosphere, but the potential for transport of MCCPs is thought to be lower than that for SCCPs.

The available evidence suggests that both SCCPs and MCCPs can undergo biodegradation, but that the rate of biodegradation may decrease with increasing chlorine content.

It is considered unlikely that LCCPs and MCCPs are degraded in the environment to shorter-chained chlorinated paraffins.

Uptake and accumulation in fish from both water and food has been demonstrated in laboratory studies for both SCCPs and MCCPs and bio-concentration factors (BCFs) of up to 7,800 and 6,600 l/kg have been measured for some SCCPs and MCCPs respectively. The BCF is expected to decrease as chain length and chlorine increase. Both SCCPs and MCCPs have been detected in a range of aquatic organisms in the environment, including marine mammals. The available information for MCCPs suggests that biomagnification is not occurring for this substance, but there is evidence of biomagnification of SCCPs in some food webs.

Both SCCPs and MCCPs are predicted to adsorb strongly to sediment and soil.

SCCPs have been shown to meet the REACH Annex XIII criteria for both PBT and vPvB substances and are currently under consideration according to the criteria for inclusion as POPs under the Stockholm Convention. The PBT and vPvB status of MCCPs under REACH is still under discussion.

Releases to the environment

CPs are released into the environment from the manufacturing of the substances, formulation (e.g. formulation of rubber or paints), applications and use of products and solid waste disposal.

An assessment of environmental releases of SCCPs or MCCPs in Denmark is not available, but has been performed in the context of the European Risk Assessment Reports (EU RAR) for the two substance groups and for the Baltic Sea Region.

The releases to the Baltic Sea Region have been assessed for the seven countries of the region. The annual emissions of SCCPs and MCCPs are estimated at about 140 – 180 t/y. The emissions of MCCPs are about ten times higher than the emissions of SCCPs and the main receiving compartment is land. For both SCCPs and MCCPs, the emissions into the Baltic environment mainly occur from products in the service and disposal phases, including emissions from 'waste remaining in the environment' e.g. particulates of polymeric products, paints and sealants containing chlorinated paraffins released during the service life of the products. The dominating industry sources of MCCPs were use as plasticisers in the manufacture of PVC and in the formulation of paints and varnishes. The main sources of SCCP emissions are articles that may have a long service life. Therefore, there will be a delay in the effect of reduced use on the yearly releases to the environment.

Emissions from municipal sewage treatment plants were of importance for SCCPs and MCCPs in some countries.

Monitoring data – levels in the environment

Chlorinated paraffins are not encompassed by the Danish NOVANA assessment programme, but a single screening study of Danish marine and fresh water sediments detected SCCPs, but not MCCPs, in sediment samples. A considerable number of monitoring data from tissues from fish, birds, and Arctic mammals, as well as sediment concentrations, are available for the Baltic and North Sea region as well as for the Arctic environment.

Total level of chlorinated paraffins in sediments from the Baltic Sea were generally higher than in those from the North Sea, but were of a similar magnitude when expressed on the basis of total organic carbon (TOC). A few sediment samples from the North Sea showed that MCCP concentrations were about twice the concentration of SCCPs.

SCCPs have also been detected in Arctic sediment samples. Tissue concentrations of chlorinated paraffins in fish liver from the North and Baltic Seas are not species-specific; levels were comparable for the North Sea and the Baltic Sea. Fish liver concentrations from remote marine areas appear to be considerably lower than samples from the North and Baltic Seas.

MCCPs and SCCPs are categorised as substances with potential for biomagnification. Generally, higher concentrations of MCCPs compared to SCCPs are found in fish tissues of the Baltic and North Seas, probably due to higher environmental releases of MCCPs.

With respect to Arctic biota, SCCPs and MCCPs could be detected and/or quantified in the majority of the samples, indicating a widespread exposure to these chemicals in the Arctic marine environment.

Biomagnification factors have been estimated for the Arctic food chain, resulting in values of about 2.3 for SCCPs and 2.0 for MCCPs.

SCCPs have been detected in Arctic air. Long-range transport and condensation effects have been mentioned among the main reasons for exposure of Arctic biota to chlorinated paraffins.

Environmental impact

The EU RAR on SCCPs (2000) concluded that there was a need for limiting the risk to aquatic organisms. Subsequently, most applications of SCCPs have been restricted.

The EU RAR from 2005 on MCCPs states that the substances have a high acute toxicity towards aquatic organisms, a high potential for bioconcentration, and are poorly degradable in the environment. The risk ratios (PEC/PNEC) exceeded 1 for several compartments, especially in the local scenarios, while no risks were identified in most of the regional scenarios.

Assessments of the risks of the SCCPs and MCCPs in the Danish, Baltic and North Sea environments have not been identified.

Human health hazard

The harmonised health hazard classifications reflect that SCCPs are suspected of causing cancer in humans, while MCCPs may cause harm to breast-fed children.

The possible carcinogenic effects of SCCPs and MCCPs have been extensively discussed. Initiated by the risk assessment process on MCCPs, the Commission Group of Specialised Experts in the fields of Carcinogenicity, Mutagenicity and Reprotoxicity agreed that there were still data gaps leading to uncertainty about the relevance for humans of kidney tumours observed in male rats, as well as inconsistencies and contradictions in the mechanistic studies, which in turn do not allow for a sufficient understanding of the carcinogenic action of SCCPs. Therefore, the Experts concluded that the criteria for no classification for SCCPs were not met, and hence recommended that the current classification of SCCPs with Carc Cat 3 should be retained. They also agreed that a read-across from SCCPs to MCCPs was not justified for carcinogenicity, and consequently MCCPs were not classified for this endpoint.

Both SCCPs and MCCPs are on the EU candidate list of endocrine disruptors. With regard to human health, both substances are categorised as CAT 1, meaning that there is evidence of endocrine disrupting activity in at least one species using intact animals.

An initial assessment of available data and the generally unreactive nature of these substances led to the conclusion that SCCPs were not mutagenic; the same applies for MCCPs. The consequences of the degree of chlorination are largely investigated.

Information on reproductive and developmental effects of SCCPs and MCCPs is sparse. A few animal studies showed that neither SCCPs nor MCCPs had an apparent effect upon fertility. Developmental effects of SCCPs have been observed at high doses (2000 mg/kg), where severe maternal toxicity was also observed. No developmental effects were observed at lower doses of SCCPs (500 mg/kg and below).

For MCCP, no adverse effects occurred during gestation in rats or rabbits in two conventional teratology studies using doses up to 5000 and 100 mg/kg/day, respectively. However, a few studies reported internal haemorrhaging, deaths in neonatal pups, and effects mediated via lactation as a consequence of maternal, treatment-related effects. Therefore, MCCPs are considered to present a hazard to the neonatal offspring via the lactating mother. The hazard to the offspring via the lactating mother is related to low vitamin K levels in the blood plasma and in the milk. A NOAEL of 47 mg/kg/day as a maternal dose has been identified for these effects mediated via lactation. The hazards result in a classification as Lact. (H362: May cause harm to breast-fed children). SCCPs are also known to be transferred to the offspring via milk. However, studies investigating the potential effects mediated via e.g. lactation are missing. Based on the similar physico-chemical properties and toxicity profiles of SCCPs and MCCPs, it is possible that SCCPs may also exert toxic effects mediated via lactation.

However, Denmark, Sweden and Norway found that the described effects concerning internal haemorrhaging and death in neonatal pups should be considered as developmental toxicity effects and not exclusively as repeated dose toxicity effects, as concluded in the RAR. However, due to mechanistic considerations, this view was not shared by the European Commission Scientific Committee on Health and Environmental Risks (SCHER).

Human exposure

SCCPs - Use of SCCPs is now restricted by legislation and future direct exposure is therefore expected to be limited. Consumers may still be exposed through finished products containing SCCPs, e.g. leather clothes in direct contact with skin, conservatively estimated to result in a maximum daily exposure of 137 mg/day assuming a leather content of 1 % SCCPs.

Indirect exposure via the environment was estimated at 20 µg/kg bw/day as a worst case estimate before the introduction of restrictions in the use of SCCPs. The available data suggest that the intake of SCCPs via food contributes substantially more to the exposure via the environment than intake via air and dust. The sources of SCCPs releases to the environment are mainly SCCPs in articles and unintentional formation during MCCP manufacture. Biomonitoring data suggest that the overall exposure levels have not changed significantly in recent years.

MCCPs - As concluded in the EU RAR, most applications of MCCPs are not designed for consumer contact. Two scenarios are considered relevant: use of metalworking fluids, expected to be an infrequent event, and wearing of leather clothes, estimated to result in dermal exposure of 1 mg/day based on content in leather of 0.0075 % MCCPs.

In a Canadian assessment, food was the major source, contributing 71 – 100% to the total intake.

SCCPs and MCCPs - Based on data from a Swedish bio-monitoring study, exposure of breast-fed babies to chlorinated paraffins (sum of SCCPs and MCCPs) was calculated as a mean intake of 0.52 µg/kg bw/day or as a maximum intake of 0.82 µg/kg bw/day, i.e. well below the established TDI (tolerable daily intake).

The median concentration of chlorinated paraffins in the indoor climate, based on findings in 40 out of 44 air samples from Sweden, was 64 ng/m^3 (5-212 ng/m^3).

Biomonitoring and trends
Studies measuring chlorinated paraffins in human breast milk from 200 Swedish women from 1996 to 2010 and 18 women from the UK from 2001 to 2002 both demonstrated that the levels of SCCPs were considerably higher than the levels of MCCPs. In Sweden, the mean concentration of SCCPs was 107 ng/g fat and the corresponding value for MCCPs was 14 ng/g fat. In the UK the analogous values were 180 ng/g fat and 21 ng/g fat, respectively. The levels for both MCCPs and SCCPs were fairly constant during the period 1996 – 2010.

Health impact
SCCPs - The EU RAR identified a possible risk in a single occupational scenario. For all other scenarios covering occupational and consumer exposures, no health risks were identified. As the production and use of SCCPs is restricted nowadays, it can be assumed that the current exposures to SCCPs do not present a human health risk (ECB, 2000).

In contrast, the Canadian environmental authorities performed a risk characterisation based on a TDI of 100 µg/kg bw/day for non-neoplastic effects of SCCPs and concluded that SCCPs constitute or may constitute a danger in Canada to human life or health (Environment Canada, 2008).

MCCPs - Only two exposure scenarios were evaluated as relevant for consumers and resulted in sufficiently high MoS-values for all relevant health effects, thus indicating no health risk for consumers. Likewise, the exposure via the environment to MCCPs as assessed in the RAR does not indicate a risk to human health.

The Canadian EPA performed a risk characterisation based on a TDI of 6 µg/kg bw/day for non-neoplastic effects of MCCPs and found that the worst-case exposure would exceed the TDI 4-fold. Therefore it was concluded that MCCPs constitute or may constitute a danger in Canada to human life or health. It is not explained why the applied TDI for MCCPs was significantly lower than the TDI for the SCCPs.

In Denmark, Nielsen and Ladefoged (2013) have calculated a TDI of 100 µg/kg bw/day for the sum of chlorinated paraffins (the combined total of MCCPs and SCCPs). The TDI is calculated based on an overall NOAEL of 10 mg/kg bw/day for effects in the liver, kidney and thyroid as well as for the effects observed in developing offspring).

SCCPs and MCCPs – Overall, indirect exposures via the environment (food, air, water) do not cause a risk to human health. Intake via food appears to be considerably more significant than uptake via air, but it is also notable that combined estimates are below the defined TDI. The same applies for infants' exposure via breast milk. However, with regard to the effects mediated via lactation, there may be uncertainty whether the TDI of 100 µg/kg bw/day is protective enough for infants. Even with a lower TDI the MoS (margin of safety) would however be high. Exposure estimates for the sum of SCCPs and MCCPs calculated in a Swedish breast milk study are as example three orders of magnitude below the TDI.

Alternatives
Overall, the few remaining applications allowing the use of SCCPs constitute a small fraction of the applications traditionally having used SCCPs. An observed decrease in SCCP consumption for conveyor belts as well as dam sealants indicates that applicable alternatives do exist. The suggested alternatives are other flame retardants recommended for use in rubber products or the complete substitution of belt material to e.g. PVC. The contacted European trade organisations have not pointed at any application where alternatives are not available.

Alternatives to MCCPs include many different compounds, since no single compound is able to provide the flame retardancy and plasticising effect needed for some applications simultaneously.

Often, LCCPs are suggested as possible alternatives, while alternative plasticiser compounds may be substituted to preserve the plasticising effect, and traditional flame retardants may be substituted to preserve the flame retarding effect of MCCPs. Other suggested MCCP alternatives are typically phosphorous compounds or sulphur-based compounds.

The requirements for performance of MCCPs in metal working/cutting fluids is a challenge, in particular for highly demanding operations, and according to the few tests conducted, alternatives for these have proved insufficient. For less demanding standard operations, alternatives to CPs have been commercialised and include sulphur-based compounds and phosphate esters and phosphonates.

A key factor in the substitution of both CPs is that they are low price chemicals for the purposes in question. For some applications, the technical performance of the alternatives is insufficient; however, for a number of applications where performance of the alternative is sufficient, the CP-containing products are still in use because they are significantly cheaper. Substituting for additively used chemicals (those not chemically reacted in the material) with a plasticiser function always require investments in finding the right re-formulation of the polymer mixture. The extra flame retarding characteristics introduce an extra factor in the re-formulation work, because other substances with flame retarding effects may need to be included in the material composition.

Main data gaps

The main identified data gaps are summarised in section 8.2. The most important data gaps concerning the need for further restriction, enforcement and management of the substances are listed below:

- Data on the remaining (exempt) uses of SCCPs in the EU are missing. It is not clear if the exemptions are still relevant.
- Data on the presence of SCCPs and MCCPs in building materials in Denmark are limited. More knowledge on where and in which quantities the substances occur in the building mass would be an advantage for the management of the substances by renovations and demolitions.
- The PBT-properties of MCCPs are currently being considered under the Substance Evaluation procedure of the REACH Regulation. As MCCPs are multi-constituent mixtures, there are uncertainties regarding both the persistence and bioaccumulation potential for MCCPs and further information is needed in order to conclude on whether or not the substance meets the P or B criteria. This information is in the process of being collected.
- Data for the further assessment of the significance of long-range transport of SCCPs and MCCPs and effects on humans and the environment in remote areas are needed.
- Tests and assessments of the technical performance of alternatives to MCCPs for some applications as well as further assessments of the environmental and toxicological aspects of substitution are needed.

Sammenfatning og konklusioner

I perioden 2012-2015 vil alle 40 stoffer og stofgrupper på Miljøstyrelsens liste over uønskede stoffer (LOUS) blive kortlagt, og Miljøstyrelsen vil på grundlag af resultaterne vurdere behovet for yderligere regulering, substitution/udfasning, klassificering og mærkning, forbedret affaldshåndtering eller øget udbredelse af information.

Denne undersøgelse vedrører kortkædede og mellemkædede chlorparaffiner (SCCP og MCCP). Disse stoffer optrådte på den første udgave af LOUS i 1999. Den første udgave af listen omfattede også de langkædede chlorparaffiner (LPPC), der senere er blevet fjernet fra listen.

Stofgrupperne
Chlorparaffiner består af en kulstofkæde, hvorpå flere af britatomerne er udskiftet med chloratomer. Kommercielle produkter er normalt blandinger af kulstofkæder af varierende længde og med varierende chloreringsgrad. De kommercielle produkter består ydermere af en kompleks blanding af isomerer og congenere (stoffer med samme længde og chloreringsgrad, men med chloratomer placeret i forskellige positioner i molekylet). Dette komplicerer vurderingerne af stoffernes toksicitet og deres skæbne i miljøet.

Traditionelt grupperes chlorparaffinerne efter kædelængde:

- Kortkædede chlorparaffiner (SCCP) med 10-13 kulstofatomer (C10-13);
- Mellemkædede chlorparaffiner (MCCP) med 14-17 kulstofatomer (C14-17);
- Langkædede chlorparaffiner (LCCP) med mere end 18 kulstofatomer.

De fleste kommercielle chlorparaffin-produkter er flydende og viskositeten af produkterne spænder fra relativt lav til meget høj. Chlorparaffiner er relativt inerte stoffer, som er resistente over for kemisk nedbrydning, og er desuden hydrolytisk stabile (har lav opløselighed i vand).

Funktionen af stofferne afhænger af den konkrete anvendelse. I plast (primært PVC), gummi, maling og fugemasser fungerer de som blødgørere med flammehæmmende egenskaber. De flammehæmmende egenskaber er af betydning for nogle anvendelser (f. eks. i artikler af gummi til minedrift og PVC i kabler), mens det i andre anvendelser er funktionen som blødgører, der er vigtigst. I metalbearbejdningsvæsker fungerer chlorparaffinerne som et smøremiddel, som forhindrer at metaloverfladerne ødelægges, når de bearbejdes under højt pres. Fordelene ved chlorparaffinerne er deres kemiske og fysiske stabilitet. I produktion af læder anvendes chlorparaffiner i læderfedtvæsker, som gør læderet vandafvisende og lysægte og gør, at overfladen føles tør.

Lovgivning
SCCP - Produktion, markedsføring og anvendelse af SCCP har i EU været forbudt siden 2012 i henhold til POP-forordningen (Forordning (EF) nr. 850/2004). Udover en generel undtagelse for stoffer og blandinger (men ikke artikler) med en koncentration på under 1 % SCCP, omfatter for-

ordningen to undtagelser: Brug som flammehæmmer i fugemasser til tætning af dæmninger og som flammehæmmer i gummi, der anvendes til transportbånd i mineindustrien.

SCCP er opført i bilag 1 til POP-protokollen til UNECE-konventionen om langtrækkende grænseoverskridende luftforurening (CLRTAP). POP-protokollen omhandler SCCP med en chloreringsgrad på mere end 48 vægt%, mens POP-forordningen omhandler alle SCCP uanset chloreringsgrad. Hverken SCCP eller MCCP er omfattet af Stockholmkonventionen. EU har foreslået, at SCCP optages under Stockholmkonventionen, og stoffet er nu under vurdering af Komitéen for Vurdering af Persistente Organiske Miljøgifte nedsat under konventionen.

SCCP er desuden omfattet af CLP-forordningen (klassificeret kræftfremkaldende og giftigt i vandmiljøet), dansk og EU-lovgivning vedrørende emissioner og miljøovervågning samt dansk og EU-arbejdsmiljølovgivning.

Svanemærkekriterierne for en række produkter sætter begrænsninger for SCCP og andre chlorparaffiner i svanemærkede produkter. EU's miljømærkekriterier nævner ikke udtrykkeligt SCCP, men stofferne er udelukket fra nogle miljømærkede produkter på grund af deres klassificering som kræftfremkaldende.

MCCP - I modsætning til SCCP, er brugen af MCCP ikke begrænset. MCCP nævnes ikke eksplicit i nogen EU-lovgivning vedrørende kemiske stoffer i produkter, emissioner eller affald. I CLP-forordningen har kun den mest anvendte af MCCP'erne (CAS nr. 85535-85-9) en harmoniseret klassificering (giftigt i vandmiljøet og mulighed for at skade børn der ammes). Selv om det ikke specifikt er nævnt, er MCCP omfattet af forskellige instrumenter. MCCP er omfattet af EU-direktivet om beskyttelse af arbejdstagernes sikkerhed og sundhed under arbejdet mod risici i forbindelse med kemiske agenser og den tilsvarende danske bekendtgørelse.

MCCP er opført i Fællesskabets rullende handlingsplan (CoRAP) under REACH af Storbritannien og stofvurderingen under REACH er i gang.

Sammen med SCCP er MCCP opført på HELCOMs liste over prioriterede miljøfarlige stoffer.

Det generelle forbud mod chlorparaffiner i en række svanemærkede produkter omfatter også MCCP. MCCP nævnes ikke direkte i nogen af EUs miljømærkekriterier og vil kunne være udelukket fra brug i nogle miljømærkede produkter som konsekvens af deres klassificering.

Fremstilling og forbrug i EU

SCCP - Den samlede registrerede produktion og import af SCCP er angivet at være inden for et mængdeinterval af 1.000-10.000 t/år. Ifølge den seneste opgørelse fra 2009 vil forbruget for anvendelser, som er undtaget fra den generelle begrænsning, ikke være mere end 400 t/år og sandsynligvis mindre. Der er ikke fundet opdaterede forbrugsopgørelser for de to undtagne anvendelser.

Som nævnt har POP-forordningen en undtagelse for stoffer og blandinger med <1% SCCP. I blandinger - såsom maling, fugemasser og lime - har SCCP typisk været anvendt som blødgører og flammehæmmer i koncentrationer væsentligt over 1%, og det forventes ikke, at blandinger med et tilsigtet indhold af SCCP under 1 % ville blive produceret eller importeret.

SCCP kan være til stede i kommercielle MCCP i koncentrationer af op til 1%, og det samlede utilsigtede indhold af SCCP i artikler og blandinger med MCCP kan være op til 0,3% (hvis blandingen eller artiklen indeholder 30% MCCP).

MCCP - Den samlede registrerede produktion og import af MCCP angives at være inden for mængdeintervallet 10.000-100.000 t/år. Det samlede produktion af chlorparaffiner i EU er cirka 45.000

t/år, og det meste af dette formodes at være MCCP. De vigtigste anvendelser af MCCP i 2006 var som blødgører/flammehæmmer i PVC (54% af det samlede forbrug i EU), i maling/overfladebelægninger, lime og fugemasser (18%), i gummi og andre polymerer (11%), som smøremiddel i metalbearbejdningvæsker (16%) og i læderfedtvæsker (1%).

Det samlede forbrug var nogenlunde konstant fra 1994 til 2006, idet et fald i forbruget til PVC blev opvejet af en stigning i forbruget til metalbearbejdningvæsker, maling/overfladebelægninger, lime og fugemasser samt tilsætningsstoffer til gummi/polymerer. Det faldende forbrug til PVC er knyttet til en udvikling, hvor ftalaterne DINP, DIDP og DPHP efterhånden har erstattet ftalaten DEHP som primær-blødgører i PVC. MCCP anvendes generelt i højere koncentrationer i PVC, hvor DEHP er primær-blødgører.

Fremstilling og forbrug i Danmark
Chlorparaffiner produceres ikke i Danmark.

SCCP - SCCP anvendes ikke til de undtagne anvendelser i Danmark. SCCP forventes ikke at blive importeret i blandinger og artikler med et tilsigtet indehold af SCCP. SCCP kan være til stede som en urenhed i artikler og blandinger indeholdende MCCP i koncentrationer af op til 0,3%.

MCCP - De samlede mængder af MCCP i blandinger, der er registreret i det danske produktregister i 2012, var 68 tons, og de vigtigste anvendelseskategorier var metalbearbejdningsvæsker, udfyldningsmidler og andre anvendelser, som blandt andet omfatter grundere og smøremidler. Der foreligger ingen data om den mulige anvendelse af MCCP i produktionen af PVC i Danmark.

Hovedparten af MCCP i blandinger og artikler, der sælges i Danmark, importeres. I en vurdering af MCCP i artikler, der importeres til Norge i 2009 blev den samlede import af MCCP i artikler anslået til 205-409 t/år; af dette blev 130-280 t/år MCCP importeret i artikler af PVC og 34-101 t/år i artikler af gummi. Tallene for Danmark er formentlig nogenlunde de samme, selv om import i gummi kan være lavere (da der ikke er egentlig minedrift Danmark).

Affaldshåndtering
SCCP - Affald med mere end 1,0% SCCP skal håndteres som farligt afffald i henhold til affaldsbekendtgørelsen. Materialer med et tilsigtet indhold af SCCP vil typisk indeholde mere end én procent af stoffet, og vil derfor skulle håndteres som farligt affald, når de bortskaffes. Selvom brugen af SCCP nu er begrænset, er materialer med SCCP blevet akkumuleret i samfundet og vil blive bortskaffet som affald i de kommende år. De vigtigste SCCP-holdige materialer akkumuleret i samfundet og til stede i affaldsstrømmen forventes at være gummi, fugemasser og lime (f.eks. i termoruder), maling og tekstiler.

Der er kun begrænset information om den faktiske tilstedeværelse af SCCP i byggematerialer i Danmark. Der er i de seneste år opbygget nogen erfaring hos danske laboratorier, hvor målinger af SCCP nogen gange foretages sammen med målinger af PCB, men disse data er ikke blevet indsamlet og sammenfattet. Data modtaget fra ét laboratorium viser, at en betydelig del af materialeprøverne fra bygninger fra perioden 1950-1977 (PCB-perioden) indeholder SCCP over detektionsgrænsen på 0,1 mg/kg.

De norske miljømyndigheder foreskriver særskilt indsamling af termoruder, der indeholder SCCP og MCCP i tilknytning til den eksisterende indsamlingsordning for PCB-holdige vinduer (Ruteretur). Endvidere indgår SCCP og MCCP i følge den norske lovgivning i de obligatoriske undersøgelser af farlige stoffer ved renovering og nedrivning af bygninger, og mængderne af chlorparaffin-holdigt affald rapporteres separat i de nationale affaldsstatistikker.

Det formodes, at noget bygge-og anlægsaffald, der indeholder SCCP (maling og fugemasse) bliver bortskaffet til materialegenvinding, og det kan ikke udelukkes, at dette kan have en indvirkning på miljøet.

MCCP – Affaldsbekendtgørelsen fastsætter ingen grænseværdier for affald, der indeholder stoffer klassificeret giftige for miljøet (som det er tilfældet for MCCP), men egenskaben "økotoksisk " er blandt de egenskaber, som kan gøre affaldet farligt. Det betyder, at det er kommunernes ansvar på grundlag af en risikovurdering at definere, om og hvornår MCCP-holdigt affald bør håndteres som farligt affald. Den samlede mængde MCCP i affaldet er op til 500 t/år; dvs. i størrelsen 5 gange højere end mængderne af SCCP i affaldet. De vigtigste affaldskategorier er artikler med PVC (herunder kabler), gummi, maling/overfaldebelægninger, lime og fugemasser.

Størstedelen af affaldet skønnes at forbrændes i kommunale affaldsforbrændingsanlæg eller deponeres, hvis MCCP forekommer i større artikler af PVC. MCCP er kun til stede i fleksibel PVC, der i øjeblikket ikke genanvendes i Danmark, når det forekommer i udtjente produkter. Både SCCP og MCCP destrueres næsten 100% ved forbrænding og forventes ikke at fungere som precursere for dannelse af dioxiner og furaner. Et hovedprodukt fra forbrændingen er hydrogenchlorid. Som alle andre klorholdige stoffer og materialer (f.eks. PVC), kan MCCP fungere som klordonorer for "*de-novo*" syntese af dioxiner og furaner i røggassen, men danske forbrændingsanlæg har udstyr til forebyggelse af dannelse og udslip af dioxiner og furaner.

Spildevand og spildevandsslam – Der er meget begrænsede tilgængelige data vedrørende SCCP og MCCP i danske kommunale rensningsanlæg. I analyser fra to kommunale rensningsanlæg var SCCP koncentrationem under detektionsgrænsen, mens MCCP koncentrationen varierede fra 500 til 810 ng/l. Der er ikke fundet analyser af chlorparaffiner i spildevandsslam i Danmark. Median niveauer af MCCP rapporteret i 2008 i norsk spildevandsslam varierede mellem 0,5 og 5,7 mg/kg med et maksimum på 11,8 mg/kg. Resultaterne indikerer en faldende tendens i forhold til de foregående år. I den norske vurdering konkluderes det, at de tilgængelige data indikerer, at der er en lille eller ingen risiko for de forskellige delmiljøer når de målte niveauer sammenlignes med relevante toksicitetsdata.

Miljømæssige effekter og skæbne

Både SCCP og MCCP er sammensatte blandinger med en variabel og ofte ukendt sammensætning, relativt lave vandopløseligheder og høje log Kow værdier. Det betyder, at fortolkningen af mange data om stoffernes skæbne og effekter i miljøet er kompliceret, da egenskaberne vil variere med kulstofkædelængde og klorindhold.

Hvirvelløse vandlevende dyr (især *Daphnia magna*) synes at være en følsom gruppe i relation til akvatisk toksicitet af både SCCP og MCCP. Den kroniske NOEC-værdi (den koncentration, hvor der ikke observeres effekter) for *Daphnia magna* er opgjort til 0,005 mg/l for SCCP og 0,010 mg/l for MCCP. Det er også blevet påvist, at MCCP er toksisk over for sedimentlevende organismer (ingen data for SCCP), og både SCCP og MCCP er påvist at medføre effekter på jordlevende organismer, men kun ved koncentrationer i størrelsesordenen flere hundrede til tusinder af mg/kg. Kombinerede virkninger som følge af samtidig eksponering for både SCCP og MCCP forventes at kunne forekomme.

SCCP og MCCP forventes at blive nedbrudt i atmosfæren ved reaktion med hydroxylradikaler med en halveringstid på 1,9-7,2 dage for SCCP og 1-2 dage for MCCP. Både SCCP og MCCP har et potentiale for langdistancetransport via atmosfæren, men potentialet for transport af MCCP menes at være lavere end for SCCP.

Den foreliggende dokumentation tyder på, at både SCCP og MCCP er bionedbrydelige, men bionedbrydningshastigheden falder med stigende klorindhold.

Det anses for usandsynligt, at LCCP og MCCP nedbrydes i miljøet til kortere chlorparaffiner.

Optagelse og akkumulering i fisk fra både vand og føde er blevet påvist i laboratorieforsøg for både SCCP og MCCP og biokoncentrationsfaktorer (BCF) på op til henholdsvis 7.800 og 6.600 l/kg er blevet målt for nogle SCCP og MCCP. BCF forventes generelt at være faldende med stigende kædelængde og chlorindhold. Både SCCP og MCCP er blevet påvist i en række akvatiske organismer i miljøet, herunder havpattedyr. De tilgængelige oplysninger om MCCP tyder på, at biomagnificering (stigende koncentrationer op gennem fødekæden) ikke sker for dette stof, men der er tegn på biomagnificering af SCCP i nogle fødekæder.

Både SCCP og MCCP forventes at adsorbere kraftigt til sediment og jord.

Det er påvist, at SCCP opfylder kriterierne i bilag XIII til REACH til både PBT og vPvB-stoffer[1] og SCCP er som nævnt for øjeblikket under vurdering i forhold til kriterierne for persistent organiske miljøgifte (POP-stoffer) i henhold til Stockholmkonventionen. PBT- og vPvB-status for MCCP under REACH er stadig under drøftelse.

Udledninger til miljøet
Chlorparaffiner udledes til miljøet fra fremstilling af stofferne, formulering (f.eks. formulering af gummi eller maling), anvendelse og brug af produkter, samt bortskaffelse af fast affald.

Der er ikke fundet vurderinger af udledningerne af SCCP eller MCCP til miljøet i Danmark, men EU risikovurderingerne for hver de to stofgrupper indeholder opgørelser af kilder til udledninger og der er desuden udarbejdet en opgørelse for Østersøregionen.

Udledninger til Østersøregionen er blevet vurderet for de 7 lande i regionen. De samlede årlige udledninger af SCCP og MCCP er omkring 140 til 180 t/år. Udledningerne af MCCP er omkring ti gange højere end udledningerne af SCCP.

For både SCCP og MCCP stammer udledningerne til miljøet i Østersøregionen primært fra produkter i brugs-og affaldsfasen, herunder udledninger i form af "affald som efterlades i miljøet", f.eks. partikler af PVC, maling og fugemasser indeholdende chlorparaffiner, som afgives ved brug af produkter. De dominerende industrielle kilder til MCCP er brug af MCCP som blødgører i fremstillingen af PVC og i formulering af maling og lak. De væsentligste kilder til SCCP-emissioner er artikler, der kan have en lang levetid. Derfor vil der være en forsinkelse i effekten af reduceret brug på de årlige udledninger til miljøet.

Udledningerne fra kommunale rensningsanlæg var af betydning for både SCCP og MCCP i nogle lande.

Overvågningsdata - niveauer i miljøet
Chlorparaffiner er ikke omfattet af det danske NOVANA overvågningsprogram, men i en enkelt dansk screeningsundersøgelse af marine sedimenter og ferskvandssedimenter blev der fundet SCCP - men ikke MCCP - i sedimentprøver. Der findes et betydeligt antal overvågningsdata af væv fra fisk, fugle og pattedyr samt koncentrationer i sedimenter for Østersøen og Nordsøen samt det arktiske miljø.

De samlede niveauer af chlorparaffiner i sedimenter fra Østersøen var generelt højere end niveauerne i sedimenter fra Nordsøen, men niveauerne var ret ens når koncentrationen blev angivet på basis af den totale koncentration af organisk kulstof. Et par sedimentprøver fra Nordsøen viser, at

[1] PBT = persistente, bioakkumularbare og toksiske i miljøet. vPvB = meget persistente og meget bioakkumulerbare.

MCCP koncentrationerne var omkring dobbelt så høje som koncentrationen af SCCP. SCCP er også blevet påvist i sedimentprøver fra Arktis.

Vævskoncentrationer af chlorparaffiner i fiskelever fra Østersøen og Nordsøen er ikke artsspecifik og niveauerne var af samme størrelse i de to farvandsområder. Koncentrationer i fiskelever fra fjerntliggende havområder synes at være betydeligt lavere end prøver fra Østersøen og Nordsøen, hvilket viser betydning af de lokale kilder.

MCCP og SCCP klassificeres som stoffer med potentiale for bioakkumulering. Generelt er der højere koncentrationer af MCCP end SCCP i væv fra fisk i Østersøen og Nordsøen, sandsynligvis på grund af højere udledninger af MCCP.

SCCP og MCCP kunne påvises og/eller kvantificeres i de fleste af de udtagne prøver fra Arktis, hvilket indikerer en udbredt eksponering for disse kemikalier i det marine arktiske miljø. Biomagnificeringsfaktorer i de arktiske fødekæder er blevet bestemt til 2,3 for SCCP og 2,0 for MCCP.

SCCP er blevet påvist i arktisk luft. Langdistancetransport og kondensationsmekanismer er blevet nævnt blandt de vigtigste årsager til eksponering af det arktiske plante- og dyreliv for chlorparaffiner.

Miljøpåvirkning
EU risikovurderingen for SCCP fra 2000 konkluderede, at der var et behov for at begrænse risikoen i forhold til vandlevende organismer. Efterfølgende er de fleste anvendelser af SCCP blevet begrænset.

EU risikovurderingen for MCCP fra 2005 angiver, at stofferne har en høj akut toksicitet over for vandlevende organismer, et høj biokoncentrationspotentiale, og er vanskeligt nedbrydelige. Risikoratioen (PEC/PNEC) oversteg 1 for flere dele af miljøet, især i de lokale scenarier, mens nogle risici blev identificeret i de fleste af de regionale scenarier.

Der er ikke fundet vurderinger af risici af SCCP og MCCP i forhold til miljøet i Danmark, Østersøen og Nordsøen.

Sundhedsfare
De harmoniserede fareklassificeringer for sundhed afspejler, at SCCP er mistænkt for at forårsage kræft hos mennesker, mens MCCP kan skade børn, der ammes.

De mulige kræftfremkaldende virkninger af SCCP og MCCP er blevet diskuteret grundigt. Igangsat af risikovurderingen af MCCP blev Europakommissionens arbejdsgruppe af specialiserede eksperter i relation til carcinogenicitet, mutagenicitet og reproduktionstoksicitet enige om, at der stadig er datamangler. Manglerne fører til usikkerhed om relevansen for mennesker af nyretumorer set hos hanrotter. Samtidig åbner uoverensstemmelser og modsigelser i de mekanistiske undersøgelser ikke mulighed for en tilstrækkelig forståelse af de kræftfremkaldende virkninger af SCCP. Derfor konkluderede eksperterne, at kriterierne for at undlade klassificering af SCCP ikke blev opfyldt, og anbefalede, at den nuværende klassificering af SCCP som kræftfremkaldende (Carc 3) bør bevares. De blev også enige om, at en analogislutning fra SCCP til MCCP var ikke berettiget for carcinogenicitet, og MCCP blev derfor ikke klassificeret for denne effekt.

Både SCCP og MCCP er på EU's liste over potentielt hormonforstyrrende stoffer. Med hensyn til menneskers sundhed er begge stoffer kategoriseret i kategori 1, som omfatter stoffer, hvor der er dokumenteret hormonforstyrrende aktivitet i mindst én undersøgelse af et levende dyr.

En indledende vurdering af tilgængelige data har ført til den konklusion, at SCCP ikke var mutagent og genotoksisk og det samme gælder for MCCP. Konsekvenser af chloreringsgrad er dog stort set ikke undersøgt.

Oplysninger om reproduktive og udviklingsmæssige effekter af SCCP og MCCP er sparsomme. Enkelte dyreforsøg har vist, at hverken SCCP eller MCCP havde en tydelig virkning på fertiliteten. Udviklingsmæssige effekter af SCCP er blevet observeret ved høje doser (2000 mg/kg), hvor også svær toksicitet hos moderdyret blev observeret. Der blev ikke observeret udviklingsmæssige effekter ved lavere doser af SCCP (500 mg/kg og derunder).

Der sås ingen negative effekter af MCCP under drægtighedsperioden hos rotter eller kaniner i to konventionelle teratogenstudier med doser på op til henholdsvis 5000 og 100 mg/kg/dag. Et par studier rapporterede dog indre blødninger, dødsfald i den neonatale afkom og effekter medieret via amning som følge af maternelle, behandlingsrelaterede effekter. De observerede blødningseffekter er relateret til et lavt indhold af vitamin K i blodplasma og i mælken. Derfor anses MCCP for at udgøre en fare for det nyfødte afkom via den ammende mor, og dette er årsagen til stoffets klassificering som Lact. (H362 : Kan skade børn, der ammes). En NOAEL på 47 mg/kg/dag (moderens dosis) er blevet fastlagt for disse effekter medieret via amning. SCCP er også kendt for at blive overført til afkommet gennem mælken. Men undersøgelser af de potentielle effekter medieret via f.eks. amning mangler. Baseret på lignende fysisk-kemiske egenskaber og toksicitetsprofiler af SCCP og MCCP, kan det betragtes som muligt, at også SCCP kan udøve toksiske effekter medieret via amning.

I Danmark, Sverige og Norge er det opfattelsen, at de beskrevne effekter vedrørende interne blødninger og død hos nyfødt afkom bør betragtes som udviklingsmæssige effekter og ikke udelukkende som toksiske effekter af gentagen udsættelse for stoffet, som det konkluderes i EUs risikovurdering. Men på grund af mekanistiske overvejelser deltes denne opfattelse ikke af Europa-Kommissionens Videnskabelige Komité for Sundheds- og Miljørisici (SCHER).

Eksponering af mennesker
SCCP - Anvendelse af SCCP er nu begrænset af lovgivningen, og derfor forventes den fremtidige direkte eksponering til stoffet at være begrænset. Forbrugerne kan stadig blive udsat for SCCP i færdige produkter, der indeholder SCCP, f.eks. lædertøj med direkte kontakt med huden, hvilket er estimeret at kunne resultere i en maksimal daglig eksponering på 137 mg/dag beregnet konservativt under forudsætning af et SCCP-indhold i læder på 1%.

Den indirekte eksponering via miljøet er blevet anslået til 20 µg/kg legemsvægt/dag som "worst case" før indførelsen af begrænsninger i brugen af SCCP. De foreliggende data tyder på, at indtagelse af SCCP via fødevarer bidrager væsentligt mere til eksponering via miljøet end indtag via luft og støv. Kilderne til udslip af SCCP til miljøet er især SCCP i artikler og utilsigtet dannelse ved produktion af MCCP. Biomoniteringsdata tyder på, at de overordnede eksponeringsniveauer ikke har ændret sig væsentligt i de senere år.

MCCP - Som konkluderet i EU-risikovurderingen er de fleste anvendelser af MCCP ikke designet til kontakt med forbrugere. To scenarier anses for relevante for forbruger: Ikke-professionel brug af metalbearbejdningsvæsker hvilket forventes at være en sjælden begivenhed, og brug af lædertøj, der skønnes at resultere i eksponering af huden på 1 mg/dag baseret på et indhold af læder på 0,0075 %.

I en canadisk opgørelse vurderedes fødevarer at være den vigtigste kilde, med et bidrag på 71 til 100% til den samlede indtagelse.

SCCP og MCCP - Baseret på data fra en svensk biomoniteringsundersøgelse, blev eksponering af babyer for chlorparaffiner (summen af SCCP og MCCP) via amning beregnet til en gennemsnitlig indtagelse på 0,52 µg/kg legemsvægt/dag eller en maksimal indtagelse af 0,82 µg/kg legemsvægt/dag, d.v.s. væsentligt under den fastsatte TDI (tolerabelt dagligt indtag).

Mediankoncentration af chlorparaffiner i indeklimaet baseret på fund i 40 ud af 44 luftprøver fra Sverige var 64 ng/m^3 (5-212 ng/m^3).

Biomonitering og udviklingstendenser

Undersøgelser af chlorparaffiner i modermælk fra 200 svenske kvinder i perioden 1996-2010 og 18 kvinder fra England i perioden 2001-2002 viste begge, at niveauerne af SCCP var betydeligt højere end niveauerne af MCCP. I Sverige var den gennemsnitlige koncentration af SCCP 107 ng/g fedt, og den tilsvarende værdi for MCCP var 14 ng/g fedt. I Storbritannien var de samme værdier henholdsvis 180 ng/g fedt og 21 ng/g fedt. Niveauerne for både MCCP og SCCP har været nogenlunde konstante i perioden 1996 - 2010.

Sundhedsrisici

SCCP - EU risikovurderingen identificerede en mulig risiko i et enkelt arbejdsmiljø-scenarie. For alle andre scenarier, der dækker erhvervsmæssig eksponering og forbrugereksponering, blev der ikke fundet nogen sundhedsrisici. Da produktionen og anvendelsen af SCCP er begrænset i dag, kan det antages, at den nuværende eksponering for SCCP ikke udgør en sundhedsrisiko for mennesker.

I modsætning hertil har de canadiske miljømyndigheder udført en risikokarakterisering baseret på en TDI på 100 µg/kg legemsvægt/dag for ikke- neoplastiske effekter af SCCP og konkluderede, at SCCP udgør eller kan udgøre en fare i Canada for menneskers liv eller sundhed (Environment Canada, 2008).

MCCP - Kun to eksponeringsscenarier blev vurderet som relevante for forbrugerne, og resulterede i høje sikkerhedsmarginer for alle relevante sundhedsmæssige effekter, hvilket indikerer, at der ikke er nogen risiko for forbrugernes sundhed. Ligeledes vurderes eksponering via miljøet for MCCP ikke at udgøre en risiko for menneskers sundhed i EUs risikovurdering.

Den canadiske EPA har udført en risikokarakterisering baseret på en TDI på 6 µg/kg legemsvægt/dag for ikke- neoplastiske effekter af MCCP og fandt, at den værst tænkelige eksponering ville overskride TDI fire gange. Det blev derfor konkluderet, at MCCP udgør eller kan udgøre en fare i Canada for menneskers liv eller sundhed. Det er ikke klart, hvorfor den anvendte TDI for MCCP er væsentligt lavere end den anvendte TDI for SCCP.

SCCP og MCCP - Samlet set vurderes indirekte eksponeringer via miljøet (mad, luft, vand) ikke at udgøre en risiko for menneskers sundhed. Indtagelse via fødevarer synes at være betydelig større end optagelse via luften, men de samlede estimerede indtag er under den definerede TDI. Det samme gælder for spædbørns eksponering via modermælken. I Danmark har Nielsen og Ladefoged (2013) beregnet en TDI på 100 µg/kg legemsvægt/dag for summen af chlorparaffiner. TDI beregnes på grundlag af en overordnet NOAEL på 10 mg/kg legemsvægt/dag for effekter i lever, nyre og skjoldbruskkirtel samt de observerede effekter på udviklingen af afkom).

Men med hensyn til mulige virkninger medieret via amning kan der være usikkerhed om, hvorvidt en TDI på 100 µg/kg legemsvægt/dag er beskyttende nok for spædbørn. Selv med en lavere TDI vil der dog være en høj sikkerhedsmargin (MoS). De estimerede eksponeringer for summen af SCCP og MCCP i en svensk undersøgelse af brystmælk var således omkring tre størrelsesordener under TDI.

Alternativer
Samlet set udgør de få tilbageværende anvendelser af SCCP en meget lille brøkdel af de traditionelle anvendelser af SCCP. Et fald i forbruget af SCCP til transportbånd samt fugemasser til dæmninger viser, at der findes alternativer. De foreslåede alternativer er enten andre flammehæmmere, som anbefales til brug i gummiprodukter, eller fuldstændig udskiftning af materialerne som transportbåndene er lavet af til f.eks. PVC. De kontaktede europæiske brancheorganisationer har ikke peget på anvendelser, hvor der ikke findes alternativer.

Alternativer til MCCP omfatter mange forskellige kemiske stoffer, da der ikke er noget enkeltstof som er i stand til at give den samtidige flammehæmmende og/eller blødgørende virkning, som er nødvendig for visse anvendelser. Ofte er LCCP foreslået som mulige alternativer, mens andre blødgørere kan erstatte MCCP hvad angår den blødgørende effekt og traditionelle flammehæmmere kan erstatte stofferne for så vidt angår den flammehæmmende effekt. Andre foreslåede MCCP alternativer end LPPC er typisk fosforforbindelser eller svovlbaserede forbindelser.

Kravene til MCCP i metalbearbejdningsvæsker gør substitution vanskelig, især for meget krævende opgaver, og alternativer til MCCP har i de få tests, der er udført, vist sig ikke at opfylde kravene i tilstrækkelig grad. For mindre krævende standardopgaver markedsføres der en række alternativer til chlorparaffiner, som omfatter svovlbaserede forbindelser, fosfatestre og fosfonater.

En vigtig faktor ved substitution af begge chlorparaffiner er, at de er lavpris-kemikalier til de pågældende anvendelser. For nogle anvendelser er de tekniske egenskaber af alternativerne ikke gode nok, men til en række anvendelser, hvor der findes alternativer med tilstrækkeligt gode egenskaber, er chlorparaffin-holdige produkter stadig i brug, fordi de er billigere. Erstatning af additivt anvendte kemikalier (stoffer, som ikke reagerer kemisk i materialet), som har en blødgørerende funktion vil altid kræve investeringer i at finde den rigtige reformulering af polymerblandingen. Det forhold, at chlorparaffinerne også har flammehæmmende egenskaber, betyder, at der er en ekstra faktor i reformuleringsarbejdet, fordi det kan være nødvendigt at tilføre andre stoffer med flammehæmmende virkning i materialet.

Vigtigste datamangler
De væsentligste identificerede datamangler er sammenfattet i afsnit 8.2. Datamangler af størst betydning i forhold til behovet for yderligere begrænsninger, håndhævelse og håndtering af stofferne er følgende:

- Der mangler data om de resterende (undtagne) anvendelser af SCCP i EU. Det er ikke klart, om undtagelserne stadig er relevante.
- Data om forekomsten af SCCP og MCCP i byggematerialer i Danmark er begrænsede. Mere viden om, hvor og i hvilke mængder stofferne forekommer i byggemassen vil være en fordel for håndteringen i forbindelse med renoveringer og nedrivninger.
- PBT-egenskaber af MCCP vurderes for øjeblikket i henhold til evalueringsprocedurerne for kemiske stoffer i REACH-forordningen. Da MCCP er blandinger, som består af stoffer med forskellige egenskaber, er der usikkerhed om såvel persistens og bioakkumulation for MCCP og der er behov for yderligere viden for at kunne konkludere, hvorvidt stoffet opfylder kriterierne P (persistent) eller B (bioakkumulerbart). Denne viden er ved at blive indsamlet som led i evalueringsprocedurerne under REACH.
- Der er behov for data til yderligere vurdering af betydningen af langdistancetransport af SCCP og MCCP og effekter på mennesker og miljø i afsidesliggende områder.
- Der er behov for yderligere tests og vurderinger af tekniske egenskaber af alternativer til MCCP til visse formål samt yderligere vurderinger af de miljømæssige og sundhedsmæssige aspekter af substitution.

1. Introduction to the substance group

1.1 Definition of the substance group

Chlorinated paraffins
Chlorinated paraffins are aliphatic hydrocarbons with a number of chlorine substitutes. Usually, they exist as mixtures of different carbon chain lengths and varying degrees of chlorination. All chlorinated paraffins have in common that no secondary carbon atom carries more than one chlorine (ECB 2000).

Commercial products contain complex mixtures of isomers and congeners, because the chlorination reaction method used for their production has low positional selectivity. Standard analytical methods do not permit separation and identification of the homologues. The amount of chlorine present in the commercial products is usually expressed as a percentage by weight (% wt), but since this refers to a mixture of carbon chain length products it is not possible to identify exactly which compounds are present in the mixture.

By convention, the following is differentiated between 3 groups is made according to chain length:

- Short-chain chlorinated paraffins (SCCPs) with 10-13 carbon atoms (C10-13);
- Medium-chain chlorinated paraffins (MCCPs) with 14-17 carbon atoms (C14-17);
- Long-chain chlorinated paraffins (LCCPs) with > 18 carbon atoms.

This report concerns only the SCCPs and MCCPs, but information on LCCPs is included when it is considered to be relevant.

A gross list of SCCPs and MCCPs has been populated on the basis of:

- The European Union Risk Assessment Report on alkanes, C10-13, chloro (ECB, 2000);
- The European Union Risk Assessment Report on alkanes, C14-17, chloro (ECB, 2005);
- "Supporting document for the draft risk profile on short-chained chlorinated paraffins" prepared for the POPs Review Committee under the Stockholm Convention (POPRC, 2010);
- All pre-registered substances which include "chloro" and "alkanes" in the name;
- An "Annex XV Restriction Report" on MCCPs submitted by the United Kingdom (UK, 2008);
- A report on CPs from Environment Canada (Environment Canada, 2008);
- A Priority Existing Chemical Assessment Report No. 16 “Short-chained chlorinated paraffins (SCCPs)” (NICNAS, 2001).

For all substances in the gross list, it has been checked whether they are pre-registered or registered under REACH. For substances imported or manufactured in the 100-1000 t/y range, the deadline for registration was 1 June 2013. The registered volume is based on the update of the registration database on the 15th of October 2013. Only two of the CAS numbers, one SCCP and one MCCP, are registered.

TABLE 1
GROSS LIST OF IDENTIFIED SCCPS AND MCCPS

CAS No	EC Number	Substance name *1	No. of C	Registered, tonnage band, t/y *2	Pre-registered
61788-76-9	263-004-3	Alkanes, chloro	no data	-	YES
68920-70-7	272-924-4	Alkanes, C6–18, chloro	C6-18	-	YES
68990-22-7	NA	Alkanes,C11-14, 2-chloro	C11-14	-	-
71011-12-6	NA	Alkanes, C12-13, chloro	C12-13	-	-
84082-38-2	281-985-6	Alkanes, C10–21, chloro	C10-21	-	YES
84776-06-7	283-930-1	Alkanes, C10–32, chloro	C10-32	-	-
85408-32-8	286-992-8	Alkanes, C8-10	C8-10	-	YES
85422-92-0	287-196-3	Paraffin oils, chloro	no data	-	YES
85535-84-8	287-476-5	Alkanes, C10-13, chloro	C10-13	1,000 - 10,000	YES
85535-85-9	287-477-0	Alkanes, C14-17, chloro	C14-17	10,000 - 100,000	YES
85536-22-7	287-504-6	Alkanes, C12-14, chloro	C12-14	-	YES
85681-73-8	288-211-6	Alkanes, C10-14, chloro	C10-14	-	YES
97553-43-0	307-202-0	Paraffins (petroleum), normal C>10, chloro	C>10	-	YES
97659-46-6	307-451-5	Alkanes, C10–26, chloro	C10-26	-	YES
104948-36-9	NA	Alkanes, C10-22, chloro	C10-22	-	-
108171-26-2	*600-857-6	Alkanes, C10-12, chloro	C10-12	-	YES

*1 As indicated by the registration

*2 As indicated in ECHA's database of registered substances.

SCCPs

SCCPs with a carbon chain length distribution consisting of 10, 11, 12 and 13 carbon atoms are typically represented by the CAS number 85535-84-8. It is the only registered SCCP. This CAS number defines the SCCPs in the EU POP Regulation and is used for the nomination of the SCCPs by the European Community for listing in Annex A of the Stockholm Convention.

The CAS no., however, does not specify the degree of chlorination (% Cl by weight) of the SCCPs, but rather represents the particular commercial SCCP products produced by chlorination of a single hydrocarbon fraction consisting of n-alkanes with the specified carbon chain length distribution (POPRC, 2010).

Figure 1 shows two examples of SCCPs with varying degree of chlorination; the upper structure is for 1,2,3,6,9-pentachlorodecane with 56% Cl and the lower structure denotes 2,5,6,7,8,9,12-hexachlorotridecane with 53% Cl by weight.

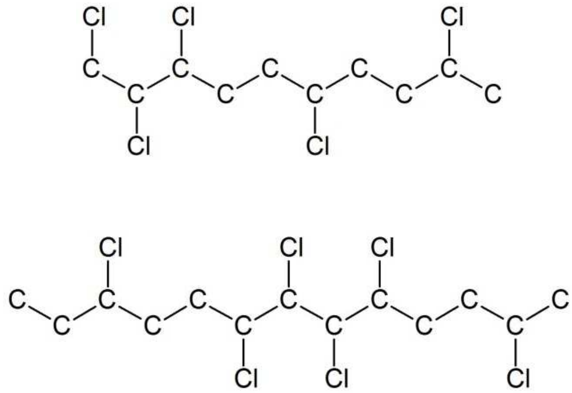

FIGURE 1
STRUCTURE OF TWO SCCP COMPOUNDS ($C_{10}H_{17}Cl_5$ AND $C_{13}H_{22}Cl_6$) (POPRC, 2010)

Since SCCP commercial products consist of mixtures of isomers and congeners, the Cl % of a product does not allow for actual identification of compounds present in the mixture. This characteristic is of importance for the evaluation of the fate and the environmental and health properties.

The EU risk assessment report on SCCPs (ECB, 2000) refers to a method for estimating the distribution of chlorine content in any given product. This method yields a prediction that approximately 80% of the isomers present lie within ±10% of the stated average chlorine content, or 90% within ±15%.

Impurities in commercial chlorinated paraffins are likely to be related to those present in the n-paraffin feedstocks. The major non-paraffinic impurity is a small proportion of aromatic hydrocarbons, typically ranging from 50-100 ppm (ECB, 2000).

The supporting document for the draft risk profile on SCCPs prepared by the Stockholm Convention Persistent Organic Pollutants Review Committee discusses different approaches for defining the SCCPs (POPRC, 2010). Whereas CAS number 85535-84-8 does not specify the degree of chlorination, two international agreements (the PARCOM Decision 95/1 and the UNECE POPs Protocol) define the SCCPs as "Chlorinated paraffins with carbon chain lengths between and including 10 and 13 and with a chlorination degree of more than 48% by weight".

In the USA, the US Toxics Release Inventory and the Action Plan for Short-Chain Chlorinated Paraffins (SCCPs) and Other Chlorinated Paraffins define SCCPs as chlorinated paraffins that meet the following definition: $C_xH_{(2x-y+2)}Cl_y$ where x = 10-13, y = 3-12, and the average chlorine content ranges from approximately 40-70%.

The present survey focuses on CAS number 85535-84-8, but has included all CAS numbers listed in Table 1 in searches in chemical databases.

MCCPs
Chlorinated paraffins with a chain length distribution of 14, 15, 16, and 17 carbon atoms are usually represented by CAS no. 85535-85-9. As for the SCCPs, the chlorination degree of neither the mixture nor the single compounds in the mixture can be determined from the CAS number. The chlorine content of the commercially available products is generally within the range 40% to around 63% by weight, but the majority of products have chlorine contents between 45% and 52% by weight. The main constituents in the majority of products have between five and seven chlorine atoms per molecule (ECHA, 2010).

Figure 2 shows two examples of MCCPs with different degrees of chlorination; the upper structure is for 2,5,6,7,10,13-hexachlorotetradecane with 53 % Cl by weight, and the lower structure denotes 2,5,6,7,8,11,15-heptachloroheptadecane with 52% Cl by weight.

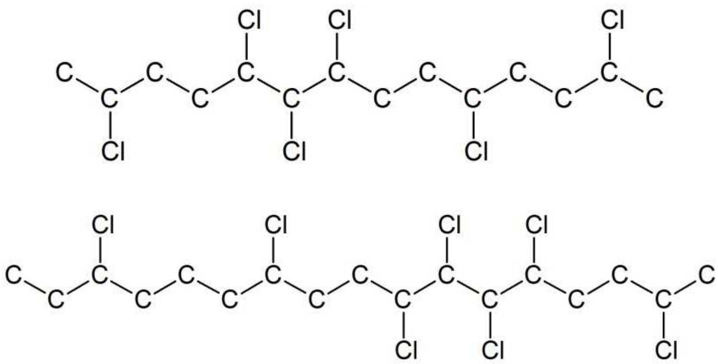

FIGURE 2
STRUCTURE OF TWO MCCP COMPOUNDS (UPPER STRUCTURE: $C_{14}H_{24}Cl_6$ AND LOWER STRUCTURE: $C_{17}H_{29}Cl_7$)

The purity of MCCP products is related to the purity of the n-paraffin feedstock from which the product is made. According to the EU Risk Assessment report on MCCPs (ECB, 2005), feedstocks contain no more than 1-2% isoparaffins (branched paraffins) and less than 100 mg aromatics/kg.

The medium-chain chlorinated paraffins may also contain <1% of chlorinated paraffins with chain lengths other than C14-17, though the actual levels are often much lower than this (ECB, 2005). The registration of CAS no. 85535-85-9 does not indicate a content of SCCPs as an impurity. The presence of SCCPs in commercial MCCPs may explain why substances or preparations containing SCCPs in concentrations up to 1 % by weight are exempt from the general restriction.

Moreover, additives such as long-chain epoxidised soya oil or glycidyl ethers are sometimes added to the commercial products at concentrations of <1% by weight in order to improve the stability of the product at elevated temperatures.

LCCPs
The long-chain chlorinated paraffins are usually identified by two CAS numbers: 85422-92-0 and 63449-39-8.

CAS No 63449-39-8 is registered with a production and import in the 10,000-100,000 t/y range. The chemical name is "Paraffin waxes and hydrocarbon waxes, chloro", but the registration indicates that the constituent is "Long-chain chlorinated paraffin". The registration does not include any information on impurities or chain length composition.

According to an environmental risk assessment of the LCCPs (Brooke *et al.*, 2009) C18–20 chlorinated paraffin products are likely to contain 1 % of C16–17 chlorinated paraffin, which is also a constituent of MCCPs. The C>20 chlorinated paraffin products are virtually free from other chlorinated paraffin impurities.

Thus the amounts of C>18 chlorinated paraffins present in SCCPs and MCCPs can be considered to be negligible (Brooke *et al.*, 2009).

1.2 Physical and chemical properties of SCCPs and MCCPs

The physical and chemical properties of chlorinated paraffins are determined by the chlorine content. Most commercial chlorinated paraffin products are liquid and range from relatively low to extremely high viscosity. There are also solid types which have longer carbon chain lengths and usually contain 70-72% chlorine (CPSG, 2013). Increasing chlorine content leads to an increase in viscosity and a decrease in volatility (CPSG, 2013). Chlorinated paraffins are relatively inert substances, which are resistant to chemical attack and are hydrolytically stable. They are liquids at room temperature and possess good thermal stability. However, kept for long periods of time at high temperature (>200°C), they will darken and release detectable quantities of hydrogen chloride. They are highly lipophilic (log Kow > 5) and have a low solubility in water.

Chlorinated paraffins are capable of mixing with many organic solvents such as aliphatic and aromatic hydrocarbons, chlorinated solvents, ketones and esters (CPSG, 2013).

SCCPs
The POPs Review Committee (UNEP, 2012b) has collected physical and chemical properties of various SCCPs congeners and mixtures, which are summarized in the following and detailed in Appendix 3. Physical and chemical properties of the main mixture, CAS number 85535-84-8, are shown in Table 2.

The degree of chlorination, the chain length distribution and possible impurities affect the physico-chemical properties of an SCCP mixture and thereby also the environmental fate.

Hilger *et al.* (2011) studied the effects of chain length, chlorination degree, and structure of SCCPs on their octanol–water partition coefficients (K_{OW}), since the K_{OW} is the key parameter determining water solubility, bioconcentration, and soil absorption. They identified a direct linear relationship between chain length and K_{OW}, while the relationship between chlorination degree and Kow was polynominal with lowest K_{OW} values around 50% Cl. As well, the position of the chlorine atoms on the alkane chain affects the K_{OW}, with more evenly distributed chlorine atoms over the whole length yielding lower K_{OW} compared to chloroalkanes, where the chlorine atoms are more concentrated in certain regions of the carbon chain.

TABLE 2
PHYSICAL AND CHEMICAL PROPERTIES OF SCCPS (ECB, 2000)

Property		Chlorine content (% wt)
EC number	287-476-5	
CAS number	85535-84-8	
IUPAC name	Alkanes, C_{10-13}, chloro	
Synonyms	alkanes, chlorinated; alkanes (C10-13), chloro-(50-70%); alkanes (C10-12), chloro-(60%); chlorinated alkanes, chlorinated paraffins; chloroalkanes; chlorocarbons; polychlorinated alkanes; paraffins-chlorinated	
Molecular formula	CxH(2x-y+2)Cly, where x=10-13 and y=1-13	
Physical state	Liquid, clear or yellowish	
Pour point (no distinct melting point) (°C)	-30.5	49
	20.5	70
Boiling point (°C)	> 200	
Flash point (closed cup) (°C)	166	50
	202	56
Relative density (g/cm³)	1.2-1.6	49-70
	1.3-1.6	52-70
Vapour pressure (at 40°C)	0.021 Pa	50
Surface tension		
Water solubility (mg/l)	0.15-0.47 (with partial hydrolysis)	
Log P (octanol/water)	4.39-6.93	49
	4.48-7.38	60
	5.47-7.30	63
	5.68-8.69	70
Molecular weight range	176.4 – 630.2 ($C_{10}H_{21}Cl$ - $C_{13}H_{15}Cl_{13}$)	

MCCPs

The physico-chemical properties for MCCPs according to the respective degree of chlorination are given in Table 3 on the basis of the EU Risk Assessment Report (ECB, 2005).

TABLE 3
PHYSICAL AND CHEMICAL PROPERTIES OF MCCPS (ECB, 2005)

Property		Chlorine content (% wt)
EC number	287-477-0	
CAS number	85535-85-9	
IUPAC name	alkanes, C14-17, chloro	
Synonyms	chlorinated paraffin (C14-17); chloroalkanes, C14-17; chloroparaffin; chloroparaffine, C14-17; medium-chain chlorinated paraffins; paraffine clorurate (C14-17); paraffine clorurate a catena media.	
Molecular formula	$C_xH_{(2x-y+2)}Cl_y$, where x = 14-17 and y = 1-17	
Physical state	Liquid	
Pour point (no distinct melting point) (°C)	-45 to 25	
Boiling point (°C)	> 200	
Flash point (closed cup) (°C)	> 210	
Relative density (g/cm^3)	1.095 at 20°C	41
	1.315 at 20°C	56
	1.1-1.38 at 25°C	40-58
	1.28-1.31 at 60 °C	56
Vapour pressure (Pa)	2.27.10^{-3} Pa at 40°C	45
	0.16 Pa at 80°C	
	1.3.10-4-2.7.10-4 Pa at 20°C	52
	1.07.10-3 Pa at 45°C	
	6.0.10-3 Pa at 60°C	
	0.051 Pa at 80°C	
Surface tension		
Water solubility (mg/l)	0.005-0.027	51
Log P (octanol/water)	5.52-8.21	45
	5.47-8.01	52
Molecular weight range	208.4-824.8 ($C_{14}H_{29}Cl$ – $C_{17}H_{19}Cl_{17}$)	

1.3 Function of the substances for main application areas

SCCPs

The remaining applications of SCCPs in the EU, according to the POPs Regulation (see next chapter) are:

- Fire retardants in rubber used in conveyor belts in the mining industry and
- Fire retardants in dam sealants.

In rubbers, the primary function of the MCCPs is to impart flame retarding properties to the rubber. Halogenated flame retardants (chlorinated and brominated) act mainly though gas phase mechanisms (Troitzsch, 2004). Due to the release of hydrogen halide during decomposition, halogen compounds act by replacing the highly reactive OH and H radicals with the less reactive halogen radical. By dissipating the energy of the OH radicals by trapping, the thermal balance is modified and this strongly reduces the combustion rate (Troitzsch, 2004).

In dam sealant the main function is as a plasticiser rather than as a fire retardant. The restriction exemption for dam sealants originates from the Parcom Decision 95/1 from 1995, where it is indicated that the function of the SCCPs is as plasticiser.

MCCPs

PVC - The main use of MCCPs is as plasticisers and flame retardants in PVC. The MCCPs impart flame retardancy, improved water and chemical resistance and better viscosity ageing stability together with a reduction in formulation cost (ECB, 2005). However, when used primarily as a flame retardant, chlorinated paraffins with high chlorine content (e.g. 70% wt. Cl) are used. As MCCPs are not produced with these high chlorine contents, they are not considered primarily as flame retardants (ECB, 2005).

Some applications make use of both their plasticising and flame retardant properties, e.g. use in PVC wall covering, PVC flooring and cables which account for about 5/6 of the total use of MCCPs in PVC (further described in section 3.3.4). MCCPs are used as secondary plasticisers in flexible PVC formulations, providing partial replacement of the more expensive phthalates or phosphate esters. Secondary plasticisers, when used in combination with primary plasticisers, cause an enhancement of the plasticising effects and so are also known as extenders (ECB, 2005).

Rubber – MCCPs are used as softener (or process oil) additives with flame retardant properties for rubber (ECB, 2005). The main application area is rubber articles for the mining industry.

Metal cutting fluids - MCCPs are used as extreme pressure (EP) additives in lubricants for metal working (Skak *et al.*, 2005). Extreme pressure additives in the lubricant prevent sliding metal surfaces from seizing under conditions of extreme pressure. At the high local temperatures associated with metal-to-metal contact, an extreme pressure additive combines chemically with the metal to form a surface film that prevents the welding of opposing asperities and the consequent scoring that is destructive to sliding surfaces under high loads (Skak *et al.*, 2005). The advantages of the MCCPs are their chemical and physical stability; they can be successfully added to most lubricants for chipless processing (multifunctionality), they are cheap and the lubricating properties of chlorinated paraffins are well documented (Skak *et al.*, 2005).

Paint, sealants and adhesives - MCCPs are used as plasticisers in paint, sealants and adhesives where the main advantages are their inertness and enhanced flame-retardant properties (CPSG, 2013).

Leather fat liquors - MCCPs are used in high-end leather products to provide light-fastness, strong binding to the leather and a dry surface feel (Entec, 2008).

2. Regulatory framework

2.1 Legislation

This section first lists existing legislation addressing short-chain and medium-chain chlorinated paraffins and provides an overview of on-going regulatory activities, focusing on which substances are in the pipeline in relation to various REACH provisions. Some background information on the different instruments and agreements is provided in Appendix 2.

2.1.1 Existing legislation

Table 5 provides an overview of existing legislation addressing SCCPs and MCCPs. For each area of legislation, the table first lists the EU legislation (if applicable) and then (as concerns directives) existing transposition of this into Danish law and/or other national rules. The latter is only elaborated upon in cases where Danish rules differ from EU rules.

Table 5 illustrates that current EU and Danish legislation mainly focuses on SCCPs (with CAS no. 85535-84-8).

SCCPs were initially regulated at the EU level in 2002 in Directive 2002/45/EC amending Council Directive 76/769/EEC (relating to restrictions on the marketing and use of certain dangerous substances and preparations), restricting their use in concentrations > 1% for applications in metalworking and fat liquoring of leather. The restriction was later included as entry 42 of Annex XVII to the REACH regulation (Regulation (EC) No 1907/2006), but this restriction has been made superfluous by the inclusion of SCCPs in Annex 1 to the POP Regulation (Regulation (EC) No 850/2004) in 2012 (Commission Regulation (EU) No 519/2012).

SCCPs have been restricted by the POP Regulation since their listing in Annex 1 of the regulation in 2012 (Commission Regulation (EU) No 519/2012). The POP Regulation is the implementing instrument in the EU for the Stockholm Convention and the POP Protocol to the UNECE Convention on Long-range Transboundary Air Pollution (CLRTAP). The listing in Annex 1 of the POP Regulation is a consequence of the listing of the SCCPs in Annex 1 to the POP Protocol. The POP Regulation generally allows low concentrations in substances and preparations (<1%). Furthermore, the Regulation provides for a general exemption from control measures if a substance occurs as an unintentional trace contaminant in substances, preparations or articles. This exemption would apply to SCCPs present as unintentional contaminants in MCCPs.

Production, placing on the market and use of SCCPs is prohibited, but subject to certain specific exemptions. The exemptions are as fire retardants in dam sealants and as fire retardants in rubber used in conveyor belts in the mining industry. Until 2015, all Member States have to report the use of SCCPs as fire retardants in rubber used in conveyor belts in the mining industry and dam sealants and document the progress of eliminating SCCPs from these applications. The POPs Regulation established concentration limits in Annex IV for substances subject to waste management provisions set out in Article 7 of the Regulation. So far, the SCCPs have not been listed in Annex IV to the POPs Regulation and consequently, no limit values have been established (see section 4.2.4 for Danish legislation relevant for SCCPs).

The POP Regulation has a slightly wider scope than the POP Protocol. The POP Protocol addresses SCCPs with a degree of chlorination of more than 48% by weight, whereas the POP Regulation addresses all SCCPs regardless of chlorination.

The first measures for monitoring the emission were introduced in 2006 with the PRTR Regulation (Regulation (EC) No 166/2006). In 2008, SCCPs were also added as priority substance under the Water Framework Directive (Directive 2000/60/EC).

Waste legislation relevant for waste-containing SCCPs and MCCPs is summarised in section 4.2.4.

TABLE 4
EU AND DANISH LEGISLATION SPECIFICALLY ADDRESSING SCCPS AND MCCPS (AS OF OCTOBER 2013)

Legal instrument *1	EU/ National	Substances (as indicated in the instrument)	Requirements as concerns SCCPs and MCCPs
Legislation addressing products			
Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes I and III (POP Regulation)	EU		The production, placing on the market and use of substances listed in Annex I, whether on their own, in preparations or as constituents of articles, shall be prohibited. The Regulation has a general exemption from control measures in the case of: (a) a substance used for laboratory-scale research or as a reference standard; (b) a substance occurring as an unintentional trace contaminant in substances, preparations or articles.
SCCPs are added to Annex I by Commission Regulation (EU) No 519/2012 of 19 June 2012 amending Regulation (EC) No 850/2004 as regards Annex I		Alkanes C10-C13, chloro (short-chain chlorinated paraffins) (SCCPs) CAS No 85535-84-8	1. By way of derogation, the production, placing on the market and use of substances or preparations containing SCCPs in concentrations lower than 1 % by weight shall be allowed. 2. By way of derogation, the production, placing on the market, and use of the following applications shall be allowed provided that Member States report to the Commission no later than 2015 and every four years thereafter on the progress made to eliminate SCCPs: (a) fire retardants in rubber used in conveyor belts in the mining industry; (b) fire retardants in dam sealants. 3. Placing on the market and use of articles produced before or on 10 July 2012 containing SCCPs as a constituent of such articles shall be allowed until 10 January 2013. 4. Placing on the market and use of articles already in use before or on 10 July 2012 containing SCCPs as a constituent of articles shall be allowed. 5. Article 4(2), third and fourth subparagraphs shall apply to articles referred to in paragraphs 1 and 2.

Legal instrument *1	EU/ National	Substances (as indicated in the instrument)	Requirements as concerns SCCPs and MCCPs
			As soon as new information on details of uses and safer alternative substances or technologies become available, the Commission shall review the derogations set out in point 2 so that the uses of SCCPs be phased out.
Legislation addressing emissions			
Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (Water Framework Directive) The SCCPs are added to Annex X of Directive 2000/60/EC as amended by Directive 2008/105/EC on environmental quality standards in the field of water policy.	EU	C10-13 Chloroal-kanes	Annex X: "List of priority substances in the field of water policy" for which measures have to be taken. Subject to Annex I "Environmental Quality standards for priority substances and certain other pollutants". Annual Average Ecological Quality Standards (AA-EQS) and Maximum Allowable Concentration (MAC) in µg/l for SCCPs are set: AA-EQS, Inland surface waters: 0.4 AA-EQS, Other surface waters: 0.4 MAC-EQS, Inland surface waters: 1.4 MAC-EQS, Other surface waters: 1.4
Bekendtgørelse om miljø-kvalitetskrav for vandom-råder og krav til udledning af forurenende stoffer til vandløb, søer eller havet [Statutory Order on environ-mental quality standards for the aquatic environments and re-quirements regarding discharges of pollutants to streams, lakes and the sea] BEK nr 1022 of 25/08/2010	National transposition of Directive 2000/60/EC		Same as Directive 2008/105/EC
Regulation (EC) No 166/2006 concerning the establishment of a Europe-an Pollutant Release and Transfer Register (PRTR Regulation)	EU	CAS 85535-84-8 Chloro-alkanes, C10-C13	The operator of a facility that undertakes one or more of the activities specified in the Regulation above the appli-cable capacity thresholds shall report the amounts annu-ally to its competent authority if the releases are above the following threshold for releases: To air: - To land: 1 kg/year To water: 1 kg/year
Bekendtgørelse om visse virksomheders afgivelse af	National supplement to	85535-84-8 Chloralkanes, C10-	See above.

Legal instrument *1	EU/ National	Substances (as indicated in the instrument)	Requirements as concerns SCCPs and MCCPs
miljøoplysninger (PRTR-bekendtgørelsen) [Statutory Order on certain companies' delivery of environ-mental information] BEK no 210 of 03/03/2010	Regulation (EC) No 166/2006	C13	
Bekendtgørelse om kvalitetskrav til miljømålinger [Statutory Order on quality requirement to environmental analyses] BEK no 900 of 17/08/2011	National transposition of various EU instruments	Chloralkanes, C10-13	Sets requirements concerning quality control of chemical analyses of environmental and product samples and requirements concerning standard deviation and detec-tion limits on the measurements. Concerns analyses prepared as part of the authorities' enforcement of the Danish Environmental Protection Act, the Chemical Substances and Products Act and other legal instruments in the field of the environment and analysis prepared as part of environmental monitoring programmes.
Bekendtgørelse om visse virksomheders afgivelse af miljøoplysninger [Statutory Order on certain companies deviations from environmental information] BEK nr 210 of 03/03/2010	National	85535-84-8 Chloralkanes, C10-C13	Companies have to report emission of substances in annex 1 (SCCPs included in annex 1), independent of whether emission limits are exceeded or not. Limits for SCCPs are 1kg/yr to both water and soil.
Legislation addressing occupational exposures			
Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC	EU	MCCPs and SCCPs	See below.
Bekendtgørelse om arbejde med stoffer og materialer (kemiske agenser) [Executive Order on Working with Substances and Materials (chemical agents)] Arbejdstilsynets bekendtgørelse nr. 292 af 26. april 2001 med senere ændringer.	National transposition of Directive 98/24/EC	MCCPs and SCCPs	The Statutory order implements the EU Directive No 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. According to the Statutory order the employer has the obligation to: - plan the work, in order to reduce any risk to the safety and health of workers arising from the presence of haz-ardous chemical agents, - replace hazardous substances, materials and work processes by less hazardous substances, materials and work processes, and - develop workplace guidelines for the use of hazardous substances and materials.
Bekendtgørelse om foran-	National	85535-84-8	Subject to Annexes 1:

Legal instrument *1	EU/ National	Substances (as indicated in the instrument)	Requirements as concerns SCCPs and MCCPs
staltninger til forebyggelse af kræftrisikoen ved arbejde med stoffer og materialer [Executive Order on measures to Protect Workers from the Risks related to Exposure to Carcinogenic Substances and Materials at Work] Arbejdstilsynets bekendtgørelse nr. 908 af 27. september 2005. med senere ændringer		Chloralkanes, C10-13	Sets conditions for certain work with chloralkanes, C10-C13 above a concentration of 0.1% chloralkanes, C10-C13 . Actual conditions may e.g. include: Laboratory work: Working processes involving substances or materials shall only take place in closed systems or in other ways preventing the release of the substances and materials so as to exclude any exposure to the effects therefrom. Metal processing: For concentrations > 1 %: Use of the substances shall not take place without the approval of the Danish Working Environment Authority. This approval cannot be assumed if the substance, material or process can be replaced by a less hazardous substance, material or working process. For concentrations 0,1-1%: The regular provisions in the occupational health and safety regulation as e.g. substitution, work place instruction and limited risks for exposure. Other Uses: Use of the substances shall not take place without the approval of the Danish Working Environment Authority. This approval cannot be assumed if the substance, material or process can be replaced by a less hazardous substance, material or working process.

*1 Unofficial translation of the titles of Danish instruments.

Standard conditions for industrial installations or activities
None of the standard conditions for industrial installations or activities listed in Annex II to the Danish Order on Environmental permitting (Godkendelsesbekendtgørelsen, BEK No 1454 of 20/12/2012) specifically address SCCPs or MCCPs (cf. Annex 5 to BEK No 486 of 25/05/2012).

Classification and labelling
Table 5 lists chlorinated paraffins for which harmonised CLP classification and labelling have been agreed upon. Harmonised classification has only been established for the SCCPs and MCCPs with CAS numbers 85535-84-8 and 85535-85-9, respectively.

TABLE 5
HARMONISED CLASSIFICATION ACCORDING TO ANNEX VI OF REGULATION (EC) NO 1272/2008 (CLP REGULATION)

Index No	International Chemical Identification	CAS No	Classification	
			Hazard Class and Category Code(s)	Hazard statement Code(s) *
602-080-00-8	alkanes, C 10-13, chloro; chlorinated paraffins, C 10-13	85535-84-8	Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H400 H410
602-095-00-X	alkanes, C 14-17, chloro; chlorinated paraffins, C 14-17	85535-85-9	Lact. Aquatic Acute 1 Aquatic Chronic 1	H362 H400 H410

* Hazard statement codes: H351: Suspected of causing cancer, H362: May cause harm to breast-fed children, H400: Very toxic to aquatic life, H410: Very toxic to aquatic life with long lasting effects.

Self classification
The Classification & Labelling (C&L) Inventory database at the website of the European Chemicals Agency (ECHA) contains classification and labelling information on notified and registered substances received from manufacturers and importers. The database also includes the harmonised classification. Companies have provided this information in their C&L notifications or registration dossiers (ECHA, 2013d). ECHA maintains the Inventory, but does not verify the accuracy of the information.

The C&L database has been searched for the chlorinated paraffins as listed in Table 1. Self-classifications of the chlorinated paraffins, for which no harmonised CLP classification and labelling have been agreed upon, are listed in the Table 6.

Please note that in some instances the substances are not classified because data are lacking. The absence of a classification e.g. for environmental hazards does not necessarily mean that the substances are not hazardous. Reference is made to the C&L inventory for more information on the self-classification of each of the substances.

TABLE 6
CLASSIFICATION INFORMATION ON NOTIFIED AND REGISTERED SUBSTANCES RECEIVED FROM MANUFACTURERS AND IMPORTERS (C&L LIST)

CAS No	Substance name (as indicated in pre-registration)	Hazard Class and Category Code(s)	Hazard Statement Codes	Number of notifiers
61788-76-9	Alkanes, chloro	**Total** Aquatic Acute 1 Aquatic Chronic 1 Aquatic Chronic 4 Lact.	 H400 H410 H413 H362	**618** 374 351 36 23
84082-38-2	Alkanes, C10-21, chloro	**Total** -	 -	**28**

2.1.2 REACH

Community rolling action plan (CORAP)

Only one MCCP is included in the Community rolling action plan (CORAP) (ECHA, 2012) for 2012, whereas no chlorinated paraffins are included in the most recent draft Community Rolling Action Plan, 2013-2015 (ECHA, 2013).

MCCPs are listed in the CORAP by the U.K and the status is indicated as "ongoing". The U.K has prepared a report following the format of an Annex XV restriction report, available at the web site of ECHA, but the front page specifically states that the report "is not a proposal for a restriction although the format is the same" (ECB, 2008a). The report is on ECHA's website designated "Annex XV transitional report". As stated in the cover page to the report, according to the REACH Regulation, the ECHA Secretariat or ECHA's Committees are neither required nor empowered to review such transitional dossiers. The Member States and the Commission are invited to use the information as appropriate. As of 25 February 2014, ECHA has published a decision on substance evaluation and requested the registrants to submit information on amounts of carbon chain lengths shorter than C14, chlorine content, robust summaries for fish feeding study bioaccumulation data, and exposure scenarios for a list of applications and lifecycle stages (ECHA, 2014). Furthermore, the registrants shall submit information using indicated test methods/instruction for bioaccumulation in fish, aerobic and anaerobic transformation in aquatic sediment systems and submit a PBT assessment.

TABLE 7
SCCPS AND MCCPS IN THE COMMUNITY ROLLING ACTION PLAN FOR 2012-2014 (ECHA, 2012A)

CAS No	EC No	Substance Name	Year	Member State	Initial grounds for concern
85535-85-9	287-477-0	alkanes, C14-17, chloro (MCCPs, Medium chained chlorinated paraffins)	2012	United Kingdom	Environment/Suspected PBT; Exposure/Wide dispersive use, high aggregated tonnage

Registry of Intentions

Table 8 shows the Registry of Intentions by ECHA and Member States' authorities for restriction proposals, proposals for harmonised classifications and labelling, and proposals for identifying chlorinated paraffins as Substances of Very High Concern (SVHC).

For SCCPs (C10-13), an Annex XV proposal has been submitted, while no current intentions exist for other chlorinated paraffins.

TABLE 8
SCCPS AND MCCPS IN REGISTRY OF INTENTIONS (AS OF 19 MAY 2013)

Registry of:	CAS No	Substances	Scope (reproduced as indicated in the Registry of intentions)	Dossier intended by:	Date of submission:
Submitted SVHC proposals					
Annex XV dossiers submitted	85535-84-8	Alkanes, C10-13,chloro [Short Chain Chlorinated paraffins] (SCCPs)	PBT	United Kingdom	26-06-2008

Candidate list
SCCPs (C10-13) have been included on the Candidate list of Substance of Very High Concern for Authorisation in Annex XIV to REACH (Table 9).

TABLE 9
SCCPS AND MCCPS ON THE CANDIDATE LIST (ECHA, 2013B; LAST UPDATED: 16/12/2013)

CAS No	EC No	Substance Name	Date of inclusion	Reason for inclusion	Decision number
85535-84-8	287-476-5	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	28-10-2008	PBT and vPvB (articles 57 d and 57 e)	ED/67/2008

Annex XIV recommendations
The latest list of Annex XIV recommendations does not include any chlorinated paraffins.

2.1.3 Other legislation or initiatives

Norway
The Norwegian building legislation includes a requirement for a survey of hazardous materials in buildings and the development of a waste management plan before demolition or renovation of buildings of more than 100 m² or generation of more than 10 tonnes of waste (Forskrift om tekniske krav til byggverk (Byggteknisk forskrift TEK 10), FOR-2010-03-26-489, chapter 9). The survey includes chlorinated paraffins. The hazardous substances to be included in the survey are defined in the waste legislation (Avfallsforskriften).

Actors in the Norwegian building sector have voluntarily phased out MCCPs in sealant foam in 2012 (Direktoratet for byggkvalitet, 2012).

2.2 International agreements

Table 10 provides an overview of the extent to which chlorinated paraffins are addressed by various international agreements.

Neither SCCPs nor MCCPs are comprised by the Stockholm Convention. However, SCCPs are proposed for listing under the Convention. The proposal addresses SCCPs products that contain more than 48% by weight chlorination (UNEP 2010).

TABLE 10
INTERNATIONAL AGREEMENTS ADDRESSING SCCPS AND MCCPS

Agreement	Substances	How the selected SCCPs and MCCPs are addressed
OSPAR Convention	SCCPs	Included in the OSPAR List of Chemicals for Priority Action (Revised 2011) Lead country for SCCPs: Sweden The OSPAR Commission has adopted a decision on SCCPs in 1995 (PARCOM Decision 95/1). Contracting Parties to the Convention decided to phase out the use of SCCPs as plasticiser in dam sealants and underground mine conveyor belts by 2004 and in all other applications by 31 December 1999.
HELCOM (Helsinki Convention)	SCCPs MCCPs	Included in the Final report of the HAZARDOUS project "Hazardous substances of specific concern to the Baltic Sea" (Baltic Sea Environment Proceedings No. 119) (HELCOM, 2009).
Stockholm Convention	SCCPs (degree of chlorination of more than 48% by weight.)	SCCPs have been nominated for inclusion in Annex A, B or C by the European Community. At the 8th meeting of the POPs Review Committee (October 2012) the POPs Review Committee concluded: "Regarding short-chained chlorinated paraffins, the Committee agreed that the information was currently insufficient to support a decision on the risk profile and agreed to consider any new information that may be made available to the Committee and to consider the chemical again at its eleventh meeting."
Basel Convention	MCCPs, SCCPs	Not specifically addressed by a waste category but may be included in various categories: Y45 "Organohalogen compounds other than substances referred to in this Annex" in the "Technical guidelines for the identification and environmentally sound management of plastic wastes and for their disposal"
UNECE Convention on Long-range Transboundary Air Pollution (CLRTAP)	SCCPs (degree of chlorination of more than 48% by weight.)	Included in Annex I and Annex II to the 1998 Aarhus Protocol on Persistent Organic Pollutants (the POPs protocol) in 2009. Annex 1: Substances scheduled for elimination. Production and use should be eliminated except for uses listed in Annex II. Annex II, substances scheduled for restriction on use. (a) Fire retardants in rubber used in conveyor belts in the mining industry; (b) Fire retardants in dam sealants. The applications are exempt on the condition that "Parties should take action to eliminate these uses once suitable alternatives are available. No later than 2015 and every four years thereafter, each Party that uses these substances shall report on progress made to eliminate them and submit information on such progress to the Executive Body. Based on these reports, these restricted uses shall be reassessed." For substances listed in Annex I each Party shall also take effective measures to ensure that destruction or disposal is undertaken in an environmentally sound manner and to ensure that the transboundary movement is conducted in an environmentally sound manner.

2.3 Eco-labels

Table 11 gives an overview of how chlorinated paraffins are addressed by the Nordic and EU eco-labelling schemes, with an indication of requirements beyond existing restrictions in the EU (the POP Regulation).

The Nordic ecolabelling criteria contain requirements which restrict the use of chlorinated paraffins for a wide range of articles. The exact criteria vary among the article groups, from specific prohibition of SCCPs to a general prohibition of halogenated organic compounds.

Chlorinated paraffins are not mentioned directly in any of the EU ecolabelling criteria for any of the product groups. However, several criteria require that the product "shall not contain substances referred to in Article 57 of Regulation (EC) No 1907/2006", i.e. substances that are on the candidate list. Furthermore, certain criteria specify hazard classes or categories and exclude "substances or mixtures meeting the criteria for classification" from the product group.

In that respect, SCCPs are comprised by a number of Ecolabelling criteria, e.g. in the EU Ecolabel for:

- copying and graphic paper (7 June 2011)
- lubricants (24 June 2011)
- newsprint paper (12 July 2012)
- wooden floor coverings (26 November 2009)
- wooden furniture (30 November 2009)
- sanitary tapware (21 May 2013).

TABLE 11
ECO-LABELS SPECIFICALLY TARGETING SCCPS AND MCCPS

Eco-label	Articles	Criteria relevant for SCCPs and MCCPs (beyond general EU restrictions)	Document title/number
Nordic Swan	Compost bins	Additives based on chlorinated or bromated paraffin ...may not be present in the plastic material.	Nordic Ecolabelling of Compost bins, Criteria document 7 June 1996 – 30 June 2014, Version 2.9
	Dish washers	Plastic parts shall not contain chloroparaffin flame retardants with chain length 10-13 carbon atoms and chlorine content > 50% by weight (CAS no. 85535-84-8).	Nordic Ecolabelling of Dishwashers, Version 3.6 • 14 March 2007 – 31 July 2014
	Floor coverings	Chlorinated/brominated paraffins, halogenated flame retardants, organic tin compounds, phthalates and fluorinated compounds must not be actively added to the floor covering.	Nordic Ecolabelling of Floor coverings, Version 5.1 • 12 October 2010 – 31 December 2014
	Furniture and fitments	The following must not be present in/added to the chemical product or material. Halogenated organic compounds in general (includes chlorinated polymers). For example: PVC, organic chloroparaffins.	Nordic Ecolabelling of Furniture and fitments, Version 4.6 • 17 March 2011 – 31 December 2017
	Heat pumps	The flame retardants... high chlorinated short-chain and high chlorinated medium-chain chloroparaffins must not be added.	Nordic Ecolabelling of Heat pumps, Version 3.0 • 13 March 2013 - 31 March 2017
	Imaging equipment	Same as for Heat pumps.	Nordic Ecolabelling of Imaging equipment, Version 6.0 • 20 June 2013 - 30 June 2016

Eco-label	Articles	Criteria relevant for SCCPs and MCCPs (beyond general EU restrictions)	Document title/number
	Panels for the building, decoration and furniture industries	The following substances must not be added to the chemical product or the material used: …, halogenated organic compounds (including chlorinated polymers) For example PVC, organic chlorinated paraffins, …	Nordic Ecolabelling of Panels for the building, decoration and furniture industries, Version 5.2 • 17 March 2011 – 30 June 2015
	Refrigerators and freezers	Same as for Dishwashers.	Nordic Ecolabelling of Refrigerators and freezers, Version 5.5 • 29 May 2008 – 31 July 2014
	Textiles, hides/skins and leather	The following chemicals must not be added: halogenated organic compounds in general (including chlorinated polymers). For example PVC, organic chlorinated paraffins, …	Nordic Ecolabelling of Textiles, hides/skins and leather, Version 4.0 • 12 December 2012 – 31 December 2016
	Toys	Prohibited substances and additives: halogenated organic compounds in general (including chlorinated polymers, PVC, chlorinated paraffins, …)	Nordic Ecolabelling of Toys, Version 2.0 • 21 March 2012 – 31 March 2016
	Washing machines	The following flame retardants may not be added to plastic materials: …, chloroparaffins with chain length 10-13 carbon atoms and chlorine content >50% by weight (CAS no 85535-84-8).	Nordic Ecolabelling of Washing machines, Version 4.7 • 18 March 2004 – 31 July 2014
	White goods	Same as for Dishwashers.	Nordic Ecolabelling of White Goods, Version 5.0 • 20 June 2013 - 30 June 2017
	Windows and exterior doors	Plastic materials must not contain additives of halogenated paraffins. This requirement does not include small plastic parts such as capping plates, clips and bricks.	Nordic Ecolabelling of Windows and Exterior Doors, Version 3.4 • 4 November 2008 – 31 December 2014

2.4 Summary and conclusions

SCCPs

Since 2012, production, placing on the market and use of SCCPs has been prohibited by the POP Regulation in the EU. Besides a general exemption for substances and mixtures (but not articles) with a concentration below 1% SCCP, the Regulation includes two exemptions: use as fire retardants in dam sealants and as fire retardants in rubber used in conveyor belts in the mining industry.

SCCPs are included in Annex 1 to the POPs Protocol to the UNECE Convention on Long-Range Transboundary Air Pollution (CLRTAP). The POPs Protocol addresses SCCPs with a degree of chlorination of more than 48% by weight, whereas the POP Regulation addresses all SCCPs regardless of degree of chlorination. Neither SCCPs nor MCCPs are encompassed by the Stockholm Convention. However, SCCPs are proposed for listing under the Convention.

SCCPs are furthermore addressed by the CLP Regulation (classification and labelling), Danish and EU emission and environmental monitoring legislation, as well as European and Danish occupational health and safety legislation.

The Nordic ecolabelling criteria for a range of products address SCCPs and other chlorinated paraffins. The EU Ecolabelling criteria do not specifically address SCCPs, but the substances are excluded from some articles due to their classification.

MCCPs

MCCPs are not mentioned specifically in any EU legislation addressing products, emissions, wastes, or occupational exposure. Without being specifically mentioned, the MCCPs are addressed by various instruments, among which are the EU Directive on protection of the health and safety of workers from the risks related to chemical agents at work and the corresponding Danish Executive Order. In the CLP regulation, only one of the MCCP mixtures (CAS no. 85535-85-9) has a harmonised classification.

MCCPs are listed in the Community Rolling Action Plan (CORAP) by the U.K and the substance evaluation under REACH is ongoing.

Together with SCCPs, MCCPs are listed specifically by HELCOM as a hazardous substance to the Baltic Sea.

The general prohibition of chlorinated paraffins in the Nordic Ecolabel criteria includes MCCPs. MCCPs are not mentioned directly in any of the EU ecolabelling criteria and might therefore be excluded from use only in ecolabelled products due to their classification.

3. Manufacture and uses

3.1 Manufacturing

3.1.1 Manufacturing processes

Chlorinated paraffins are manufactured by adding chlorine gas to the base paraffin in a stirred reactor. Depending on the chain length of the paraffin feedstock, the temperature of the reaction is maintained between 80 and 100°C, with cooling if necessary. Catalysts are not usually needed for the reaction to proceed, but ultraviolet light may be used to aid the reaction.

Once the desired degree of chlorination has been reached (as determined by density, viscosity or refractive index measurements), the flow of chlorine gas into the reaction is stopped. Air or nitrogen is then used to purge the reactor of excess chlorine and hydrochloric acid gas and small quantities of a stabiliser (e.g. epoxidised vegetable oil) may be added to the product. The product is then typically filtered and piped to batch storage tanks for filling drums, tankers or bulk storage tanks (ECB, 2005).

3.1.2 Manufacturing sites

According to the Chlorinated Paraffins Sector Group (part of Euro Chlor), the major manufacturers of chlorinated paraffins in the EU (including long-chain chlorinated paraffins) are INEOS Chlor (United Kingdom and France), Caffaro (Italy), Química del Cinca (Spain), Leuna Tenside (Germany) and Novácke Chemické Závody (Slovak Republic) (CPSC, 2013). Outside the EU the major producers are Dover Chemicals in North America, NCP Exports in South Africa and Orica in Australia. There are numerous other producers in Asia, principally in India, China, Taiwan (Handy) and Japan (Tosoh).

MCCPs are registered by 11 companies, including those mentioned above, except for Novácke Chemické Závody. According to Entec (2008), MCCPs were produced by five companies within the EU in 2008.

SCCPs are registered by one company only, INEOS Chlorvinyls Limited (UK). The company has recently stopped production.

Information on the actual manufacturing sites has not been collected.

3.1.3 Manufactured volumes in the EU

The Chlorinated Paraffins Sector Group has been contacted for updated information on the manufacture and use of SCCPs and MCCPs in the EU. The organisation has answered that it is not in a position to provide information for the survey, and refers to the information in registrations.

According to the organisation's website, the total EU production of chlorinated paraffins is approximately 45,000 t/y.

SCCPs

The total registered manufacture and import of SCCPs is indicated to be within the tonnage band 1,000-10,000 t/y (Table 1).

Based on consultation and literature review, Zarogiannis and Nwaogu (2010) concluded that the level of production of SCCPs in the EU was about 1,500 tonnes in 2009. With the recent restriction on the use of SCCPs, the manufactured volume today is probably considerably lower.

MCCPs

The total registered manufacture and import of MCCPs is indicated to be within the tonnage band 10,000-100,000 t/y (Table 1).

In 2006, Euro Chlor (2008b) indicated that 63,691 tonnes of MCCPs were sold in the EU25 (ECB, 2008).

3.1.4 Global manufacturing volume

The global manufacturing and use of SCCPs and MCCPs may provide an indication of the possible import of SCCPs and MCCPs in mixtures and articles.

SCCPs

No data on the total global production of SCCPs are available. The revised draft risk profile from the POPs Review Committee states that CPs (of various chain length) are produced in the EU, North America, China, India, Japan and Brazil (UNEP, 2012b). The risk profile mentions that twenty manufacturers in India have a combined installed capacity of 110,000 tonnes of CPs per annum, but no specific information on SCCPs is given. None of the information on the use of SCCPs in various countries indicates that SCCPs are used for application areas other than the areas known from use in Europe.

MCCPs

No data on the total global production of MCCPs are available.

MCCPs in flexible PVC articles may perhaps be more prevalent in articles produced outside the EU, because there, the phthalate DEHP constitutes a major part of the PVC plasticisers (Lassen *et al.*, 2010). As of 2007, DEHP constituted only about 17% of the total Western European plasticiser demand, whereas globally it still constituted about 50% of the demand (Lassen *et al.*, 2010).

A market survey for chlorinated paraffins in China shows that the chlorinated paraffins (probably mainly MCCPs) accounted for about 10% of the plasticizer market in that country (CCM Chemicals, 2006 – only a part of the report has been available). In the EU, at the same time, MCCPs took up about 6% of the plasticizer market. The differences in the percentages may reflect the differences in the consumption pattern for phthalates; DEHP took up 79% of the total market in China, while in the EU, DEHP accounted for less than 30% of the total market. Furthermore, the market survey mentions that many downstream users replace a larger proportion of the DEHP with chlorinated paraffins because of their lower price (CCM Chemicals, 2006).

The data indicate that MCCPs may be found in a larger proportion of products of flexible PVC produced in China as compared to products produced in the EU.

3.2 Import and export

Chlorinated paraffins have been registered earlier under the CN customs code 382390 85 “Liquid polychlorobiphenyls, liquid chloroparaffins; mixed polyethylene glycols” (Intrastat, 1994). In the recent nomenclature, chlorinated paraffins are not included (Commission Regulation (EU) No 1006/2011). It has therefore not been possible to identify import and export data for chlorinated paraffins for either Denmark or the EU.

SCCPs
Based on consultation and literature review, Zarogiannis and Nwaogu (2010) concluded that the level of production of SCCPs in the EU in 2009 was about 1,500 tonnes. In relation to exports, based on an EU consumption of about 530 tonnes in 2009 (as further discussed in section 3.3.1, exports of SCCPs to non-EU customers were calculated at 970 t/y. Zarogiannis and Nwaogu (2010) did not estimate the import, but noted that in the past, imports of SCCPs from non-EU countries have been very small, but that the decreasing size of the relevant markets could make the role of SCCPs imports much more significant, even though the total volume used is smaller.

MCCPs
No updated information on the import and export of MCCPs has been identified.

Entec (2008) estimated that just over 60% of the EU production of MCCPs was sold in the EU with the remaining (around 36,000 t/y) exported to outside the EU in 2008. The report does not provide any information on import.

3.3 Uses of SCCPs and MCCPs

3.3.1 Consumption of SCCPs in the EU
The estimated consumption of SCCPs by application area in 2009 is shown in the Table 12. As further described in section 3.4 on the historical trends, until 2000 the main application area of SCCPs was in metal working lubricants, a practice which has been banned since 2004. For the remaining applications the total consumption has been fairly constant during the period 2003-2009.

As a consequence of the restriction, the only remaining applications of SCCPs are as fire retardants in rubber used in conveyor belts in the mining industry and as fire retardants/plasticiser in dam sealants.

The European Tyre & Rubber Manufacturers' Association (ETRMA) and the Association of the European Adhesive & Sealant Industry (FEICA) have been contacted for information on the two exempt applications. FEICA has stated that the organisation has no information indicating that SCCPs are still used in sealants. According to ESWI (2012), 5-20% of the tonnage sold to the sealants industry before 2010 was associated with dam sealants (spillways and sea defence).

TABLE 12
ASSUMED EU CONSUMPTION OF SCCPS BY APPLICATION IN 2009 (ZAROGIANNIS AND NWAOGU, 2010)

Application	Sales of SCCPs in the EU, t/y	% of total
Sealants and adhesives	237	45%
Paints	101	19%
Rubber	162	31%
Textiles	29	6%
Total	530	100

3.3.2 Applications of SCCPs
The use of SCCPs in metalworking fluids and fat liquors for leather has been banned in the EU for a decade, and the remaining volumes in products in use today are considered limited.

As SCCPs may still be present in in buildings, construction and articles in use in society, the former use of SCCPs in long-lasting materials and articles is briefly described below.

Sealants and adhesives

According to Zarogiannis and Nwaogu (2010), the literature suggests use of SCCPs in polysulphide and polyurethane formulations as well as acrylic and butyl sealants. The relevant applications in 2010 were filling of expansion and movement joints in building and general engineering, the filling of joints for protection from spillages, and where resistance to water, chemicals, alkalis, solvents and biological agents is required and where low temperatures may prevail, the waterproofing of roofs, and adhesives suitable for a variety of substrates. The main use of SCCPs is thought to be in sealants rather than adhesives (BRE *et al.*, 2008).

Chlorinated paraffins with high chlorine contents were also used in sealants for double and triple-glazed windows (ESWI, 2011; BRE *et al.*, 2008), but it has not been possible to confirm that it was actually SCCPs which were used for this application.

Concentrations of 20-30% SCCPs appeared to be common for sealant and adhesives. Information from one source only indicates that the degree of chlorination of the SCCPs used is 56% but could well be higher.

Zarogiannis and Nwaogu (2010) obtained information on the use of SCCPs in the Czech Republic, France, Germany, the Netherlands and the UK and estimated that there were 20 formulators of sealant and adhesives in the EU using SCCPs.

With particular regard to the two applications that are now exempt from the POP Regulation, Zarogiannis and Nwaogu (2010) state that a major manufacturer of conveyor belts has indicated that transition to MCCPs was smooth and low cost, and two other companies were working on alternatives in 2010. None of the companies identified appeared to offer dam sealants. As mentioned above, FEICA has stated that the organisation has no information indicating that SCCPs are still used in sealants.

Paints

SCCPs were used in chlor-rubber and acrylic protective coatings as well as in intumescent paints.

Typical applications included road marking paints, anticorrosive coatings for metal surfaces, swimming pool coatings, decorative paints for internal and external surfaces, and primers for polysulphide expansion joint sealants. SCCPs may also be used in cross-linkable polyester systems with peroxides for the production of long-term road markings and may be found in unsaturated polyester resin, used in the production of fibre reinforced composites. Road marking paints appeared to be a key application (Zarogiannis and Nwaogu, 2010).

SCCPs generally acted as plasticisers and reduced the cost of the formulation by (partly) replacing primary plasticisers such as phthalates.

In intumescent coatings, the concentration of SCCPs ranged between 2.5% and 10%. In road marking paints the concentration could be fairly low, from <1% to 10%, but typically towards the lower end of this scale. In anti-corrosive and protective coatings, SCCPs concentrations could be 10-15%. Information from Euro Chlor (as reported by Zarogiannis and Nwaogu, 2010) suggests that the typical level of chlorinated paraffins in the formulated paint would be 4-15% by weight. After drying (evaporation of solvent), the chlorinated paraffin content of the coating would be around 5-20% by weight.

Consultation suggests SCCPs concentrations of 50% to 54% in paints but could be considerably higher for water repellence or fire retardancy (e.g. intumescent paints). The literature suggests that the number may be as high as 70%.

Zarogiannis and Nwaogu (2010) obtained information on the Czech Republic, Spain and the UK, whereas indirect consultation with distributors has confirmed the use of SCCPs in paint manufacture in France and Slovenia. They estimated that there are 20 formulators of paint in the EU that use SCCPs.

Rubber

The literature suggests use of SCCPs in underground mining conveyor belts (the only current exemption) and products such as gaskets, hoses etc.

Zarogiannis and Nwaogu (2010) have confirmed the use of SCCPs in conveyor belts in the EU and had received indications that use in other products was still occurring in 2010. They assumed that conveyor belts accounted for 75-90% of the consumption for rubber in 2010. Among the different types of conveyor belts, use of SCCPs has been confirmed in mono-ply (solid woven) conveyor belts (the most modern type). In these, a textile core is impregnated with PVC and is then covered with a rubber cover. Zarogiannis and Nwaogu (2010) assume that any recycling of SCCP-containing rubber, especially conveyor belts, is unlikely to occur in appreciable quantities.

The typical concentration of SCCPs is 10% for conveyor belts and 10-17% for other rubber products. The literature indicates a high chlorination degree of 63-71%; consultation of Zarogiannis and Nwaogu (2010) with companies suggested levels of 60-65% only and information from the Bulgarian authorities suggested levels of 52-56% by weight (past use).

In 2010, two conveyor belt manufacturers appeared to continue using SCCPs (Zarogiannis and Nwaogu, 2010). Both companies were in the process of switching to alternatives (possibly MCCPs). France, Germany, Poland and the UK were countries using SCCPs (although companies located in some of these countries may have already discontinued the use of SCCPs in 2010). Zarogiannis and Nwaogu (2010) estimated 3 users in the EU of SCCPs for production of conveyor belts and 10 users for production of other rubber products (the latter now banned).

Textiles

Typical applications of SCCPs potentially included furniture upholstery, seating upholstery in transport applications, and interior textiles such as blinds and curtains as well as industrial protective clothing.

Zarogiannis and Nwaogu (2010) suggested that use in the impregnation of commercial and military tents (to provide a flame retardant, waterproof and rot-proof finish – ‘dry proofing’ of heavy textiles) was still ongoing in 2010. On the other hand, continued backcoating of upholstery or industrial textiles (workwear) was considered unlikely by Zarogiannis and Nwaogu (2010). The types of fibres impregnated with SCCPs may have been polyester-cotton, cotton or linen-flax.

Literature suggests concentration of SCCPs at 4-15% and a chlorine content of around 56-60% chlorine by weight for backcoating of textiles (Zarogiannis and Nwaogu, 2010).

According to Zarogiannis and Nwaogu (2010), one major tent textile processor used SCCPs in the UK in 2010. Another user was located in France (according to information from a distributor). Past users in countries such as Belgium, France, Germany and the Netherlands had apparently moved on to alternatives by 2010.

3.3.3 Consumption of MCCPs in the EU

The trend in demand in the EU for MCCPs from 1994 to 2006 by major use category is summarised in Table 13. Updated figures have been requested from Euro Chlor, but no data have been obtained. The total consumption remained stable from 1997 to 2006; a decline in the use for PVC was counterbalanced by an increase in the consumption for metal working/cutting fluids, paints/coatings, adhesives and sealants, and additives for rubber/polymers. The increase in demand for these three application areas is partly due to a shift from the use of SCCPs to MCCPs (see section 3.4).

The major use of MCCPs in articles is as co-plasticiser, used together with phthalates in PVC. As shown in the table, the demand for MCCPs for PVC is generally declining in the EU. The reason may be that MCCPs are less compatible with primary plasticisers such as DINP (MCCPs User Forum, 2003, as cited by Entec, 2008). The decrease in the use of MCCPs may likely be a consequence of the gradual replacement of DEHP by DINP and other higher phthalate plasticisers (Lassen *et al.*, 2010). According to information obtained from industry, MCCPs are used with DINP and DIDP; however, the compatibility in DINP and DIDP is not as good as with DEHP, so formulators tend to reduce the amount of MCCPs in the formulation if they are switching to higher phthalates (DINP, DIDP and DPHP).

As of 2007, DEHP constituted only about 17% of the total European plasticiser demand, whereas globally it still took up about 50% of the demand (Euro Chlor, 2010 as cited by Lassen *et al.*, 2010). This indicates, as mentioned above, that MCCPs in flexible PVC articles may perhaps be more prevalent in articles produced outside the EU.

The declining trend in the use of MCCPs for PVC has likely continued since 2006. The increasing trend for the other applications may not have continued as the application of SCCPs (and thereby the potential for substitution) was very limited in 2006.

TABLE 13
TRENDS IN DEMAND FOR MCCPS IN THE EU BY OVERALL APPLICATION CATEGORY (ENTEC, 2008)

Application	EU 1994 *1 Tonnes	EU 1997 *1 Tonnes	EU 2003 *2 Tonnes	EU 2006 *3 Tonnes	EU 2006 % of total
Additives for PVC	45,476	51,827	32,450	34,676	54%
Metal working/cutting fluids	2,611	5,953	8,113	9,907	16%
In paints/coatings, adhesives and sealants	3,079	3,541	8,236	11,323	18%
Additives for rubber/polymers (other than PVC) *3	2,497	2,146	3,521	7,077	11%
In leather fat liquors	1,614	1,048	1,411	708	1%
In carbonless copy paper	1,296	741	89	-	-
Total	56,573	65,256	53,820	63,691	100%

Notes from Entec (2008)

*1: ECB (2005).

*2: Cefic (2004). Data for 2003 included 2,894 t categorised as 'other'. This is understood to relate to unidentified sales through distributors and not to different uses. This has been distributed amongst the other applications on a pro-rata basis.

*3: Euro Chlor (2008a; EU25). Data are for the EU-25 whereas previous estimates are assumed to be for the EU-15. The data listed as “rubber/polymers” are referred to as “flame retardant textiles and rubber” in the 2006 data. Data for 2006 include 9% categorised as “other and unknown” which has been assumed to be distributed proportionately amongst the other uses.

Examples of the use of MCCPs in individual Member States and Norway are shown in Table 14. Though not explicitly reported as such, these data should all likely be interpreted as demand for MCCPs as chemicals, not including MCCPs in imported articles (Lassen *et al.*, 2010).

It is notable that the use of MCCPs for production of PVC in Germany, Austria, Sweden and Norway accounted for a significantly smaller percentage of the total than the EU average, whereas the percentage of the total used for production of PVC is significantly higher in the UK. The EU Risk Assessment Report (ECB, 2005) indicates that the main user countries in 1999 were Italy and the UK, with the use in the UK accounting for just over 25% of the total EU use. However, according to the data presented in Table 13and Table 14, the UK accounted for 18% of the total EU consumption in 2003 and on a per-capita basis, the use in the UK is only slightly over the EU average (Lassen *et al.*, 2010).

The data indicate that there might be some regional differences in the use of MCCPs as co-plasticisers in PVC, which may be correlated with a shift in the use of the phthalates from DEHP to the heavier types of phthalates DINP and DIDP as the primary plasticisers (Lassen *et al.*, 2010).

TABLE 14
EXAMPLES OF NATIONAL DEMAND FOR MCCPS BY APPLICATION CATEGORY IN EU MEMBER STATES AND NORWAY (ENTEC, 2008)

Application	Germany & Austria (2006) *1 Tonnes	Sweden (2005) *2 Tonnes	Norway (2005) *3 Tonnes	UK (2003) *4 (approximate) Tonnes
PVC	1,136	3.5		8,000
Metalworking fluids	1,136	65.8	5	1,500
Paints, sealants and adhesives	2,272	22.8	31-36	300
Rubber/polymers other than PVC	1,670		15-20	100
Leather fat liquors	<66.81			0
Other and unknown	401	2	3	100
Total	**6,681**	**94.1**	**54-64**	**9,968**

Notes from Entec (2008):

*1 Euro Chlor (2008). The data listed as “rubber/polymers” are referred to as “flame retardant textiles and rubber” in the source data.

* Kemi (2008). Note that the 3.5 t indicated as used in PVC is cited as used in “plastics” in the reference.

*3 SFT (2007).

*4 MCCPs User Forum 2003 (sales data, extrapolated from data up to September 2003).

3.3.4 Applications of MCCPs

PVC

MCCPs are used as secondary plasticisers in flexible PVC formulations, providing partial replacement of the more expensive phthalates. They do not impart flexibility to the PVC resin alone but, when combined with a primary plasticiser, will act in such a way as to add flexibility to the final product. The majority of secondary plasticisers in use are chlorinated paraffins chlorinated to a level of 30-70%. The MCCPs impart flame retardancy, improved water and chemical resistance and better viscosity ageing stability alongside a reduction in formulation cost (ECB, 2005). If the main function is flame retardancy, usually long chained chlorinated paraffins (LCCP) with high chlorine content are used (ECB, 2005).

Use of MCCPs with different chlorination in PVC - The EU Risk Assessment Report, RAR (ECB, 2005) reports that MCCPs with different chlorine contents are used for different applications:

- For soft PVC products that require a high flexibility at normal and low temperatures, MCCPs with chlorine contents around 40-45% chlorine by weight are used as secondary plasticiser. Examples of applications for this type of PVC include coatings, some types of flooring, garden hose and shoe compounds. The secondary plasticiser is added at 10-15% by weight of the total plastic.

- MCCPs with higher degrees of chlorination (typically around 50-52% wt. Cl) are more compatible with PVC and have a lower volatility than lower chlorinated analogues. They are used as secondary plasticisers in calendered flooring, cable sheathing and insulation and in general-purpose PVC compounds. In products with a high filler content, such as some types of calendered flooring, they can be used as the sole plasticiser at levels of around 10% in the finished product.

- The more highly chlorinated MCCPs (e.g. 56-58% wt. Cl) are less volatile still and are used for softening plastics that are subject to higher temperatures during processing (not further specified).

According to Entec (2008), flooring, wall coverings and cables accounted for 5/6 of the MCCPs used in PVC. The same product groups accounted for about 37% of the end use of DEHP in 2006 (COWI *et al.*, 2009).

According to Entec (2008), PVC flooring containing MCCPs represented 9-14% of PVC flooring sales while PVC cable compounds containing MCCPs represented around 5-7% of cable sales in 1999.

Metal working/cutting fluids
Metalworking fluids remove deformation heat and friction heat arising during cutting and, additionally, flush away chips and prevent dusting.

MCCPs can be used in neat and water-emulsifiable metalworking fluids, as well as greases and gear oils for industrial and automotive applications (Houghton, 2003 as cited by Entec, 2008). They are used in concentrations from a few percent to nearly 100% and enhance lubrication and surface finish in extreme-pressure metalworking and forming applications. The release of chlorine by frictional heat provides a chloride layer on the metal surface, reducing friction levels at the contact points between tool and workpiece and between tool and chip. They can be used across a wider temperature range than many alternatives and are particularly suitable for low temperature applications. Typical operations including use of MCCPs include deep drawing, stamping, forming and broaching (CSF, 2002 as cited by Entec, 2008).

Rubbers
MCCPs are used in different types of rubbers such as nitrile rubber, natural rubber and styrene-butadiene rubber. In rubbers, the primary function of the MCCPs is to impart flame retardant properties to the polymers (Entec, 2008). Short-chain, medium-chain and long-chained paraffins are (or have been) used as flame retardants in the rubber industry (Brooke *et al.*, 2009).

Based on a survey among their member companies, the European Tyre & Rubber Manufacturers Association, ETRMA, has stated that MCCPs are used as flame retardants in all rubber applications in the mining industry (ETRMA, 2010 as cited by Lassen *et al.*, 2010). One example of application in the mining sector is conveyor belts (on chloroprene, styrene-butadiene rubber, nitrile rubber, or butadiene rubber polymer basis). In the mining sector the concentration of MCCPs can vary from 2-3% up to 5-10% w/w depending on the specific application/article.

According to ETRMA, other applications of MCCPs as flame retardants in rubber include (Lassen *et al.*, 2010):

- Rubber tapes for road markings in concentrations of 3-4%. The road markings are applied on the road by means of adhesives. They are used for marking the road; for instance, the yellow lines applied on the road in case of roadwork.
- Offshore hoses in concentrations of approximately 9%.
- Sheeting in concentrations of approximately 9%. The sheets with MCCPs are used for applications where fire protection is required. An example mentioned is rubber flooring in buildings.

ETRMA furthermore stated that MCCPs are not used in tyres. ETRMA have been contacted for updated information in this study, but no information has been obtained.

According to Entec (2008), identified examples of MCCPs' uses in end-products included conveyer belts, tubes for compressed air in the mining industry, bellows for busses, metros and trains, and rubber profiles for fireproof doors. The chlorinated paraffins used generally have a high chlorine content and are present at concentrations of up to 15% w/w (ECB, 2005).

A survey of the use of chlorinated paraffins (short-, medium- and long-chained) in the rubber industry in the UK identified the following uses of MCCPs (Brooke *et al.*, 2009):

- Cable cover in a concentration of 3.8%
- Rubber hoses in a concentration of 6.2%
- In pipe seals in a concentration of 4%
- Industrial rollers in concentrations of up to 20%
- Flame retardant items for railway use in a concentration of 7.2% MCCPs.

The EU consumption of MCCPs as additives for rubber and polymers other than PVC increased from 1994 to 2006 from about 2,500 tonnes (EU15) to about 7,000 tonnes (EU27). The consumption in Germany was equal to the EU per capita average, whereas the consumption in the UK was considerably lower. No breakdown of the consumption of MCCPs in rubber by application area in the EU has been available.

Textiles and fabric

Flame retardant textiles have been mentioned as an application of MCCPs (Euro Chlor, 2008, as cited by Entec, 2008). According to the EU RAR (ECB, 2005), information provided from a supplier of MCCPs indicated that around 6.6% of the total MCCPs supplied for PVC applications was used in textiles (probably backcoating) and coated products. The risk assessment assumed an average thickness for this type of product of 1 mm and a MCCPs content of 10-15% for the calculation of releases.

According to a Danish study from 2002 on alternatives to phthalates in the textile and clothing industry, PVC containing phthalates plasticisers were used at that time for PVC coated textiles such as tents, tarpaulins, rainwear and work clothes (Hansen and Høg Lejre, 2002). According to the study, chlorinated paraffins (type not specified) may be used as secondary plasticisers in the products because they reduce overall material costs (MCCPs are cheaper than phthalates), provide improved fire properties, and improve the resistance against microbial degradation.

MCCPs have been identified in a number of textile products in Norway (Lassen *et al.*, 2010). For those applications, it is most likely that the use of MCCPs has been as plasticiser in PVC coatings.

The concentration in the fabric (including both the textile and the coating) was on average 0.5%. The explanation for the relatively low concentration may be that the MCCPs are present only in the thin coating, but at higher concentrations. Chlorinated paraffins may also be used in impregnation to provide water proofing (a function other than the water proofing provided by the PVC coating) and fire proofing, but for these applications long-chained chlorinated paraffins have mainly been used (Brooke *et al.*, 2009).

PVC coated textiles and fabric may either consist of an outer surface of textile with a PVC backcoating (e.g. used in bags) or with the coating forming the outer surface with a textile back (e.g. used in rainwear or imitation leather fabric).

Leather fat liquors

MCCPs are used in high-end leather products to provide light-fastness, strong binding to the leather and a dry surface feel. Alternatives are natural oils. MCCPs are used for this purpose in some EU countries, but use has been abandoned in others, e.g. in the UK (MCCPs User Forum, 2002, as cited by Entec, 2008). Around 2006, up to 10% of the total EU production of leather may have contained MCCPs. That year, 84% of the EU leather production took place in Italy. Other major producers were Spain and Germany. Around 12 kg MCCPs are used per tonne of "wet blue" (wet, freshly tanned leather (Entec, 2008)).

According to the revised EU risk assessment, around 3% of fat liquor is present in the formulation that is added to raw leather, of which approximately 10% consists of MCCPs. Around 2-2.5% of the added formulation is taken up by the leather. Therefore, the amount of MCCPs present in the leather is about 0.0075% (ECB, 2008). It is odd that only 2-5% is taken up by the leather, as the MCCPs have a function in the final leather product. A Risk Reduction Strategy for the use of SCCPs in leather states that when applied to the leather, between 95% and 99% of the SCCPs may be taken up by the leather. The EU Risk Assessment for SCCPs indicates that the SCCP content of leather goods is up to 1% (ECB, 2000). For LCCPs, Brooke *et al.* (2009) indicates that 98% of the LCCPs are taken up by the leather and the concentration in the final leather would, based on the presented data, be some 0.7-1.2%.

Most likely, the EU Risk Assessment for MCCPs have mixed up the percentage taken up by the leather with the percentage leaving with the wastewater, and the concentration in the final products are more likely comparable with the concentration of SCCPs and LCCPs when used as leather auxiliaries. Using the data provided in the EU Risk Assessment, the content of the final leather product may be estimated at around 0.3%.

According to COTANCE/UNIC (in: Entec, 2008), the chlorinated paraffins most used for leather are the heavier LCCPs (chain length above 17).

For the survey in Norway, COTANCE (2010 as cited by Lassen *et al.*, 2010) has stated that when used in the leather industry, chlorinated paraffins are/were part of chemical preparations marketed by major chemicals suppliers for certain process steps. Precise content of MCCPs in such preparations is generally not known to the user and COTANCE did not hold any specific information on the MCCPs' use.

COTANCE was contacted for updated information in this study, but no information has been obtained.

Paints

MCCPs are used in paints based on various types of resin. The MCCPs act as a plasticiser to reduce cracking and detachment of the paint. Typical applications are reported to be chlorinated rubber-based paints used in harsh marine and industrial environments, and vinyl-copolymer paints used on exterior masonry (Lassen *et al.*, 2010). Concentrations of MCCPs in paints are typically 1-5% by weight, but may be up to 25%. Other specific uses reported are for paints for concrete sealing/coating, primers and coatings for structural steel, roof coatings, above waterline marine coatings, antifouling paints, acrylic and epoxy underwater primers, swimming pool paints, masonry paints, chemical resistant coatings, high humidity resistant coatings, security fencing paints, damp-proof paints, floor coatings and flame retardant coatings for wood and paper (Entec, 2008, and various sources cited therein).

For a study on MCCPs in articles in Norway, the association of manufacturers of paints, printing inks and artists' colours in Europe, CEPE, has indicated that MCCPs are used mainly in industrial coatings including e.g. marine coatings and protective (anti-corrosion) coatings (Lassen *et al.*, 2010). The organisation states that, to their knowledge, no simple substitutes for the MCCPs' uses in these coatings are available. This information has been confirmed by the organisation for this study.

Brooke *et al.* (2008, citing BCF 1999) gives information on the typical types of paint that may contain chlorinated paraffin. Note that the examples refer to all types of chlorinated paraffins and not just MCCPs. These are summarised in the table below. All paints are organic solvent-borne.

TABLE 15
CHLORINATED PARAFFIN CONTENT OF PAINTS AND COATINGS (BCF, 1999 AS CITED BY BROOKE *ET AL.*, 2008)

Coating type	CP content (% by weight)
Organic solvent borne chlorinated rubber primers and topcoats	1–5
Organic solvent borne chlorinated rubber systems for swimming pools/fishponds	5–20
Organic solvent borne zinc rich (epoxy) primers	2–5
Organic solvent borne acrylic container coatings	2–10
Organic solvent borne chemical and water resistant coatings	5–20
Organic solvent borne vacuum metallising lacquers	1–5
Organic solvent borne flame retardant coating for wood	1–5
Organic solvent borne intumescent coating for structural steel	20–30
Organic solvent borne floor paints	5–10
Organic solvent borne water-proofing coatings for walls	5

Sealants and adhesives
Primary uses in this category are sealant-type products (which are also used as adhesives), such as polysulphide sealants, polyurethane sealants, acrylic sealants and butyl sealants used in building and construction. This includes use in double and triple glazed windows. They are primarily used for their plasticising and flame retardant properties (Houghton, 2003, as cited by Entec, 2008).

3.3.5 Consumption of SCCPs and MCCPs in Denmark

No recent assessments of the consumption of SCCPs and MCCPs in Denmark are available.

An older assessment of the use of CPs in Denmark provides consumption figures by application area for LCCPs (CAS No 63349-39-8), but otherwise only addresses the CPs in common (Back *et al.*, 1995).

Data from the Danish Product Register
Data on chlorinated paraffins registered in the Danish Product Register were retrieved in November 2013 on the basis of the gross lists of chlorinated paraffins shown in Table 1.

The Danish Product Register includes substances and mixtures used occupationally and which are imported or produced in quantities above 100 kg/year and contain at least one substance classified as dangerous in a concentration of at least 0.1% to 1% (depending on the classification of the substance). Both SCCPs and MCCPs, with the respective CAS numbers 85535-84-8 and 85535-85-9, are classified as dangerous. For the other non-classified substances, the registration will only occur if they are constituents of mixtures which are classified and labelled as dangerous due to the presence of other constituents. Solid polymer compounds and masterbatches used in the production of plastics are not covered by demands for notification to the Product Register. The data consequently do not provide a complete picture of the presence of the substances in mixtures placed on the Danish market. As stated above, the amounts registered are for occupational use only, but for substances used for the manufacture of mixtures in Denmark, the data may still indicate the quantities of the substances in the finished products placed on the market both for professional and consumer applications.

The data for 2012 were retrieved directly from Danish Product Register while data from the previous years were retrieved from the SPIN database, which holds non-confidential information from the product registers of the Nordic countries.

According to data from the SPIN Database (based on data from the Product Registers of the Nordic Countries), the total annual registered consumption of SCCPs (CAS 85535-84-8) in Denmark has been continuously decreasing over the last decade with a total reported use of 23.5 tonnes (2000), 11.0 tonnes (2005), 5.1 tonnes (2010), and 4.8 tonnes (2011).

Figure 3 shows the consumption of SCCPs by reported use category in Denmark (only non-confidential data). The figures from the SPIN database (2000-2010) indicate that consumption of SCCPs has ceased in Denmark. The figures from the product registry (2012) indicate continued use of SCCPs in cooling and cutting agents, as well as <0.5 tons of filling and padding agents. These figures, however, could also have been caused by a missing update of the database and probably do not reflect the actual use situation. Whereas data for volumes of products are regularly updated in the Product Register, data on the composition of the products is not updated regularly, and may be outdated.

The consumption of MCCPs (CAS No 85535-85-9) is significantly higher with total registered use tonnages of 42.8 tonnes in 2011 and 68 tonnes in 2012. The non-confidential data are shown in Figure 4. The total registered quantities in the SPIN database fluctuate during the period 2000-2011 (increases e.g. from 58.5 tonnes in 2001 to 54,697 tonnes in 2002). This variance is presumably due to flawed registration in the database.

MCCPs are used in a wide range of industrial applications. About 34 tonnes were used in cooling and cutting agents for metal processing according to data from the product registry, while consumed filling and padding agents comprised a total of 30 tonnes. From 2009 on, the category "Paint, lacquers and varnishes" is not indicated as a use category when using the national categories (shown in the table). The data represented by the common UC62 categories, however, still indicate some tonnes used for paint, lacquers and varnishes in 2009 and 2011. The explanation for this result may be some differences in the grouping of the applications, and consequently, some differences in confidentiality.

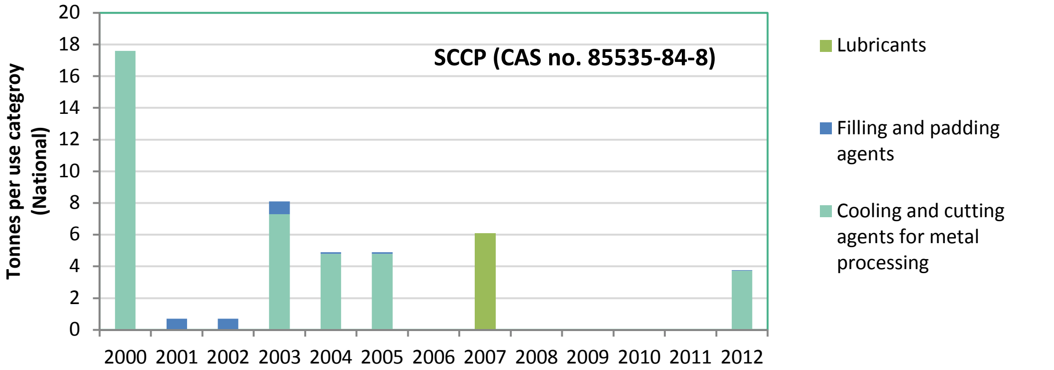

FIGURE 3
USE OF SCCPS IN DENMARK PER USE CATEGORY (NATIONAL; NON-CONFIDENTIAL DATA FROM THE SPIN DATA-BASE, EXCEPT FOR 2012 DATA WHICH ARE FROM THE PRODUCT REGISTER)

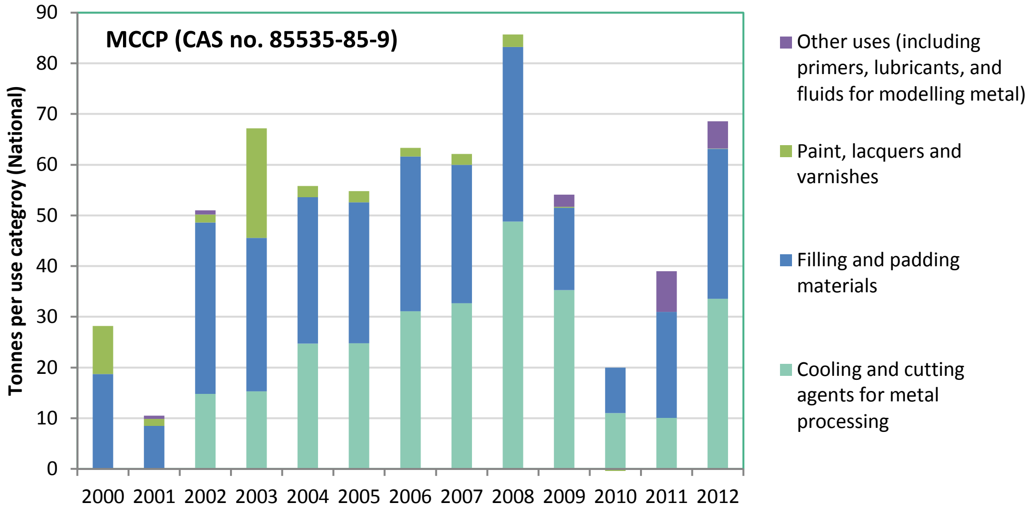

FIGURE 4
USE OF MCCPS IN DENMARK PER USE CATEGORY (NATIONAL; NON-CONFIDENTIAL DATA FROM THE SPIN DATA-BASE, EXCEPT FOR 2012 DATA WHICH ARE FROM THE PRODUCT REGISTER)

Apart from SCCPs and MCCPs, production and import of chloroalkanes with unspecified chain length (CAS 61788-76-9) are also registered in the product register (Table 16). The reported use categories are similar to the categories for MCCPs, and the main application is in metal cutting fluids.

TABLE 16
SCCPS AND MCCPS IN MIXTURES PLACED ON THE DANISH MARKET IN 2012 AS REGISTERED IN THE DANISH PROD-UCT REGISTER

CAS No	Chemical name	No of mixtures	Registered tonnage, t/y		
			Produc-tion + import	Export	Consump-tion *1
61788-76-9	Chlorinated alkanes, unspecified	4	22.9	0	22.9
85535-84-8	Alkanes, C10-13, Chloro-	8	2.6 - 4.9	0	2.6 - 4.9
85535-85-9	Alkanes, C14-17, Chloro-	77	59.6 – 64.4	7.2 – 9.5	52.4 – 54.9
Total		**88**	**85.1 – 92.2**	**7.2 – 9.5**	**77.9 – 82.7**

*1 Total content of mixtures placed on the Danish market

Raw materials for PVC and rubber production
MCCPs in solid polymer compounds and masterbatches used for plastics and rubber production in Denmark would not be registered in the Product Register. MCCPs are likely present in raw materials for production of plasticised PVC in Denmark and perhaps also in raw materials for rubber production. The Danish Plastics Federation and the PVC Information Council have been contacted. No specific information on quantities of MCCPs consumed in production of plastic raw materials has been obtained. The organisations have established contact with European manufactures of MCCPs.

3.3.6 Imported articles

SCCPs
The restriction of SCCPs in articles and mixtures has an exemption for substances and mixtures containing less than 1% SCCPs. Based on the description of the former uses of SCCPs in the EU, mixtures with an intentional content (technical function) of SCCPs would contain more than 1%.

According to the EU Risk Assessment for SCCPs, the SCCP content of leather goods is to a maximum of 1% (ECB, 2000). The exemption, however, does not concern SCCPs in articles and the leather goods would not be covered by the exemption.

SCCPs may be present as an impurity in articles and mixtures containing MCCPs. As commercial MCCPs may contain up to 1% SCCPs as impurities, articles and mixtures with MCCPs may contain SCCPs in concentrations up 0.3% (if the mixture or article contains 30% MCCPs.

MCCPs
A majority of the MCCPs in mixtures and articles sold in Denmark may be imported. In an assessment of MCCPs in articles imported to Norway in 2009, the total import of MCCPs in articles was estimated at 205-409 t/y. It was estimated that 130-280 t/y MCCPs were imported with articles of PVC and 34-101 t/y in articles of rubber, thus accounting for the majority of MCCPs in imported articles (Lassen *et al.*, 2010). The majority of the PVC articles were imported from the EU because the product groups with a high volume (flooring, wall covering, cables) were predominantly imported from the EU. Import statistics for product groups estimated to account for 70-90% of the import of flexible PVC showed that of the total tonnage of products, 84% was imported from the EU and Switzerland, while 9% was imported from China. articles imported from China were toys and sports products, clothing and bags (85% from Asia).

The situation in Denmark is probably quite similar.

3.3.7 MCCPs in consumer products

Due to the restriction, intentionally added SCCPs should not be present in any consumer products marketed today. The restriction has an exemption for trace content.

MCCPs may primarily be present in articles with MCCP-containing PVCs, but may also be present in some sealants used by consumers, and articles of rubber and leather.

A survey of chemical substances in sealants analysed for CAS No 85422-92-0, which is a CP of undefined length, but considered by Euro Chlor to be a LCCP. In 2 of 18 screened sealants, the CP was found in concentrations of 5 and 9 %, respectively (Nilsson *et al.*, 2004). The two sealants with CP were of the foam type.

In one of the surveys, "Mapping of chemical substances in animal care products" it is briefly mentioned that a few of the products contained SCCPs, but the concentrations were not quantified (Nylén *et al.*, 2004).

Articles of PVC
MCCPs may be present in virtually any type of article containing plasticised PVC as a co-plasticiser together with phthalates. The MCCPs are generally present in higher concentrations in PVC containing the phthalate DEHP than in PVC with higher concentrations of the phthalates DINP, DIDP and DPHP.

Apart from products listed below in the categories of clothing, travel goods and other textile articles, a range of consumer products with PVC may contain MCCPs:
- Flooring and wall coverings;
- Electric wires and cables;
- Garden hoses and other hoses and profiles;
- Products of PVC foils: Swimming pools, water beds, etc.
- Shoe soles and other moulded products of PVC.

In the EU Risk Assessment, it was assumed that consumer exposure to MCCPs in PVC products is likely to be minimal because the products are not used for food contact purposes and have low leaching rates. The assessment, however, was not based on actual analyses of leaching rates and may be questionable.

Clothing, travel goods and other articles of coated fabric
MCCPs may be present in clothing, travel goods and other articles of coated fabric. MCCPs have been identified in a number of textile products in Norway (Lassen *et al.*, 2010). The products are typically imported; likely, the situation in Denmark is quite similar to the situation in Norway. As mentioned in the section on applications, the concentration in the fabric (including both the textile and the coating) was on average 0.5%. The explanation for the relatively low concentration is likely that the MCCPs are present only in the thin coating, but at higher concentrations.

Examples of PVC coated fabric products used by consumers are shown below. For some of the product groups, surveys of MCCPs in products in Norway have demonstrated that MCCPs are present at least in some products (indicated with an *), whereas for other products no evidence of the use of MCCPs has been identified (Lassen *et al.*, 2010). This does not rule out that they may be used, however:

- Bags*, backpacks*, briefcases, purses* and suitcases
- Rainwear and water resistant gloves*
- Shoes, boots and waders
- Table cloths and aprons
- Venetian blinds, curtains, shower curtains and similar items
- Tents
- Camping chairs*
- Air mattresses
- Imitation leather fabric used in clothing, bags and furniture
- Awnings, canopies and tarpaulins.

Paints – MCCPs are used mainly in industrial coatings including e.g. marine coatings and protective (anti-corrosion) coatings. The paints are usually not the kind purchased by consumers, and an Internet search for safety data sheets has not revealed any paints containing MCCPs specifically for consumers. The EU Risk Assessment mentions that an exception is in the use of some paints used for coating swimming pools. In Denmark, however, consumers may use some MCCP-containing marine coatings for leisure boats to a limited extent.

Sealants and filling materials
MCCPs are used in different types of sealants. The sealants types which are mentioned in the literature (polysulphide sealants, polyurethane sealants, acrylic sealants and butyl sealants) are generally

used in building and construction and may to a limited extent be used by consumers for do-it-yourself activities. An Internet search for safety data sheets have identified MCCP-containing fire-retardants (PU foams) which are also sold to consumers.

Rubber
MCCPs are used as a flame retardant in rubbers, and the main applications are in the mining industry and in means of transport. Rubber cables (usually used for outdoor purposes) may to some extent be used by consumers and analyses of rubber cables marketed in Norway have demonstrated MCCPs in concentrations of 2.6-11% (Lassen *et al.*, 2010).

Leather
MCCPs may be present in articles of leather such as shoes, coats and trousers. Actual analyses of MCCPs in leather goods have not been identified. As mentioned earlier, according to the EU Risk Assessment, the concentration should typically be 0.0075% in leather articles treated with MCCPs, but this concentration seems to be based on a mistake. Based on the data provided in the EU Risk Assessment, the content of the final leather product may be estimated at around 0.3%, which is consistent with reported concentrations of SCCPs and LCCPs in leather. The consumer exposure to MCCPs in leather is further discussed in section 6.2.1 on human exposure.

Other
An Internet search for safety data sheets identified MCCP-containing bicycle oil sold to consumers.

The EU Risk Assessment indicated that metal working fluids may be used by non-professionals to a limited extent e.g. for car restoration.

3.4 Use of long-chain chlorinated paraffins

Long-chain chlorinated paraffins (LCCPs) are not within the scope of this survey. The CPs are however often, in particular in the historical literature, addressed together and for this reason some information on the use of LCCPs is provided here, based on an environmental risk evaluation of LCCPs (Brooke *et al.*, 2009).

About 5,000–10,000 tonnes of LCCPs were used in the EU each year for the years 1998–2004. The exact usage figures were considered as confidential information. The consumption of LCCPs has been on a level of 10-20% of the consumption of MCCPs for the years 1998-2004.

The relevant CAS No 63449-39-8 is registered with a total import and production in the 10,000-100,000 t/y range (ECHA Dissemination Database).

The main current areas of use are as a secondary plasticiser in PVC (about 10% of the total), as a flame retardant in rubber (about 35% of total), as a plasticiser/flame retardant in paints (about 30%) and sealants/adhesives (about 8%), as an extreme pressure additive to metal cutting/working fluids (about 5%), as a component of leather fat liquoring treatments and for waterproofing textiles. In very general terms, the chlorinated paraffins with chlorine contents in the range 40–50% wt. Cl are used in plasticising applications, whereas the chlorinated paraffins with very high chlorine contents (e.g. 70% wt. Cl) are used mainly as flame retardants.

3.5 Historical trends in use

Few data on the historical use of the CPs before 1990 have been identified.

The Environmental Health Criteria for CPs from 1996 mention that liquid chlorinated paraffins were first used in large amounts during the period 1914-1918 as solvents for Dichloramine T in antiseptic nasal and throat sprays (IPCS, 1996). The commercial production of chlorinated paraffins for use as extreme pressure additives in lubricants started around 1930 (IPCS, 1996).

Kirk Othmer Encyclopedia of Chemical Technology (2003) indicates that CPs have been manufactured on a commercial basis for over 50 years (i.e. dating back to earlier than 1953). The early products were based on paraffin wax feedstocks and used as fire retardants and plasticizers in surface coatings and textile treatments and as extreme pressure–antiwear additives in lubricants.

Campbell and McConnel (1980) estimated the global production of CPs at 230,000 tonnes in 1977. Of this approximately 26% was SCCPs, 48% MCCPs and 26% LCCPs.

Around 1990 about 15% of the European consumption of chlorinated paraffins was estimated to be SCCPs, 70% was MCCPs and 15% LCCPs (IPCS, 1996).

Data indicating when the use of CPs for the different applications in Europe started have not been identified.

SCCPs
Data on the sale of SCCPs in the EU for the period 1994 to 2009 is shown in Figure 5.

The key drivers behind these changes have been (Zarogiannis and Nwaogu, 2010):

- The classification of the substance in the early 1990s as a carcinogen and dangerous to the aquatic environment (N; R50/53). Especially in the metalworking fluids sector, downstream users wanted safer materials and manufacturers started focusing on longer-chain chlorinated paraffins;
- The results of the EU Risk Assessment under the Existing Substances Regulation (ESR) which resulted in an EU-wide restriction on the use of SCCPs in metalworking fluids and leather fat liquors. Use in metalworking fluids (theoretically) ceased in the EU in 2004 while use in leather fat liquors effectively ceased in 2001.

Information from key industry associations presented by BRE *et al.* (2008) suggests that sales of SCCPs have been decreasing due to substitution mainly by MCCPs.

From 2003 to 2009 the consumption levels in the remaining applications has been fairly stable, as illustrated in Figure 6.

For use in paints, sealants and adhesives (of particular interest for the discussion of SCCPs in waste) the consumption dropped from a level of 900-1800 t/y in 1994-2002 to a level of 200-300 t/y in 2003-2009. No data on consumption before 1994 is available.

By the inclusion of SCCPs as persistent organic pollutants to Annex 1 of the POPs protocol in June 2012, the only exempt applications of SCCPs are as fire retardants in rubber used in conveyor belts in the mining industry and as fire retardants in dam sealants.

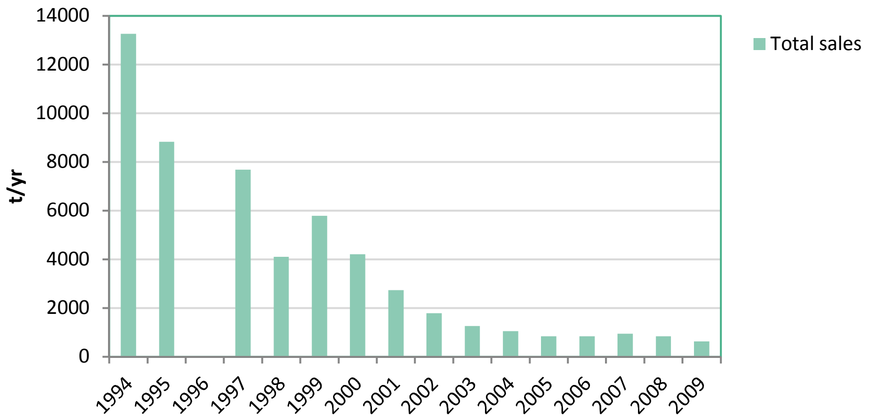

FIGURE 5
TOTAL ANNUAL SALES OF SCCPS IN THE EU IN 1994-2009 (REDRAWN FROM ZAROGIANNIS AND NWAOGU, 2010; DATA MISSING FOR 1996)

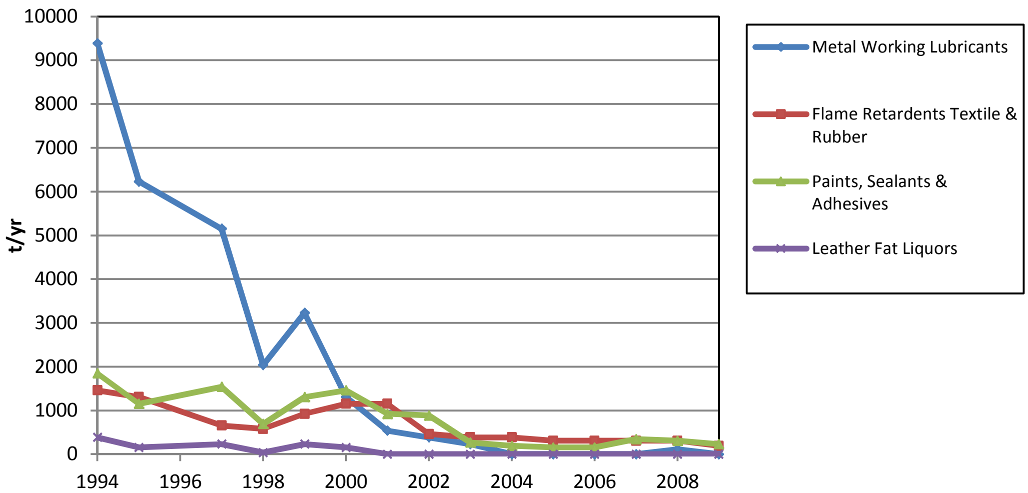

FIGURE 6
ANNUAL EU CONSUMPTION OF SCCPS PER APPLICATION IN 1994-2009 (REDRAWN FROM ZAROGIANNIS AND NWAOGU, 2010; DATA MISSING FOR 1996)

Trend data for Denmark are shown in Figure 3. The data shows a similar downward trend.

MCCPs

The trend in demand for MCCPs in the EU from 1994 to 2006 distributed by major use category is summarised in Table 13. Updated figures have been requested from Euro Chlor, but no data have been obtained. It is expected that the decreasing trend in the use of MCCPs for PVC has continued and is partly correlated with the decreasing trend in the use of DEHP as primary plasticiser.

Trend data for Denmark are shown in Figure 4. In accordance with the EU data, the total consumption is fairly stable.

3.6 Summary and conclusions

Manufacture and consumption in the EU

SCCPs - The total registered manufacture and import of SCCPs in the EU are indicated to be within the tonnage band 1,000-10,000 t/y. According to the most recent assessment from 2009, the consumption for applications now exempt from the general restriction would be no more than 400 t/y. Updated consumption data for the two exempt applications, in rubber used in conveyor belts in the mining industry and in dam sealants, have not been obtained.

As mentioned, the EU restriction of SCCPs has an exemption for substances and mixtures with <1% SCCPs. In mixtures such as paint, sealants and adhesives, SCCPs have typically been used as plasticisers and flame retardants in concentrations well above 1%, and it is not expected that mixtures with an intentional content of SCCPs below 1% would be produced or imported.

SCCPs may be present in commercial MCCPs in concentrations of up to 1%, and the total unintentional content of SCCPs in articles and mixtures with MCCPs may be up to 0.3% (if the mixture or article contains 30% MCCPs.)

MCCPs - The total registered manufacture and import of MCCPs is indicated to be within the tonnage band 10,000-100,000 t/y. The total EU production of chlorinated paraffins is approximately 45,000 t/y and of this, the majority is considered to be MCCPs. The principal uses of MCCPs in 2006 were as plasticisers/flame retardants in PVC (54% of total), in paints/coatings, adhesives and sealants (18%) and rubber and other polymers (11%), as lubricant in metal working/cutting fluids (16%) and in leather fat liqueurs (1%).

The total consumption remained stable from 1994 to 2006, when a decline in the consumption for PVC was counterbalanced by an increase in the consumption for metal working/cutting fluids, paints/coatings, adhesives and sealants and additives for rubber/polymers. The downward trend in the consumption for PVC happened simultaneously with a trend whereby the phthalates DINP, DIDP and DPHP have gradually substituted for DEHP as primary plasticisers. The MCCPs are generally used in higher concentration in PVC where DEHP is the primary plasticiser.

Consumption in Denmark

CPs are not manufactured in Denmark.

SCCPs – SCCPs are not used for exempt applications in Denmark. SCCPs are not expected to be imported in mixtures and articles intentionally containing SCCPs. SCCPs may be present as an impurity in articles and mixtures containing MCCPs in concentrations of up to 0.3%.

MCCPs – The total quantity of MCCPs in mixtures registered in the Danish Product Register in 2012 is 68 tonnes, and the main use categories were cooling and cutting agents, filling and padding materials and other uses including primers, lubricants and fluids for modelling metals. Apparently the consumption in paint, lacquers and varnishes ceased in 2008. No data are available on the possible use of MCCPs in the production of PVC in Denmark.

A majority of the MCCPs in mixtures and articles sold in Denmark may be imported. In an assessment of MCCPs in articles imported to Norway in 2009, the total import of MCCPs in articles was estimated at 205-409 t/y; of this, 130-280 t/y MCCPs were imported with articles of PVC and 34-101 t/y in articles of rubber. The figures for Denmark are probably quite similar although the import via rubber may be lower (as there are no mining activities in Denmark).

Data gaps

Data on the remaining (exempt) uses of SCCPs in the EU are missing. It is not clear if there is still a need for the exemptions.

Updated data on the consumption of MCCPs by application area at the EU level are not available in the public domain. The data may be available for the authorities associated with the joint REACH registration of the main substance.

Data on the use of MCCPs for the production of articles of rubber and PVC in Denmark are not available.

4. Waste management

4.1 Waste from manufacture and industrial use

SCCPs

The quantity of SCCP-containing waste from manufacture and industrial use in the EU in 2010 has been estimated as part of an assessment undertaken for the European Commission (ESWI, 2011). The waste, in total 62 t/y, originates from the production of rubber (mainly conveyor belts for the underground coal mining industry): 14 t/year, production of sealants and adhesives: 12 t/y, production of paints and varnishes: 30 t/y and production of textiles: 5.8 t/y. Due to the restriction, SCCPs are no longer used for production of paint, varnishes and textiles.

The concentration of SCCPs in the majority of the waste from manufacturing and industrial use ranges from 2-50 %. As concentrations of SCCPs higher than 1 % in waste renders the waste hazardous, the production waste having SCCPs concentration higher than 1 % should be classified as hazardous and treated as such.

MCCPs

No updated data on the quantities of waste from manufacture and industrial use of MCCPs are available.

4.2 Waste products from the use of SCCPs and MCCPs in mixtures and articles

4.2.1 SCCPs in waste in the EU and Denmark

Estimated SCCPs accumulation in products in society in the EU in 2010 and total quantities disposed of as solid and liquid waste is shown in Table 17 based on an assessment undertaken for the European Commission (ESWI, 2011). For the sealants, adhesives and paint, the estimate is based on consumption figures for the period 1994 to 2010 (shown in section 3.5) and would underestimate the actual quantities because much of the building materials used before 1994 would still be present in the buildings. Historic data on the use of SCCPs in Europe and Denmark before 1994 for these applications are not available, but all available information indicates that SCCPs may have been used for several decades before 1994.

Based on the results of the assessment, the majority of the waste is landfilled (67 %) and the remaining part is incinerated. Only a minor quantity is disposed of at hazardous waste incineration plants. The distribution between the different waste treatment methods is valid for EU25 and different from the situation in Denmark, primarily as concerns the use in rubber for conveyor belts. The different treatment methods applied in Denmark are described in Table 18 and in Table 19 for SCCPs and MCCPs, respectively.

TABLE 17
SCCPS ACCUMULATED IN SOCIETY AND DISPOSED OF AS SOLID WASTE IN 2010 IN EU25 (ESWI, 2011)

	Accumulated in products in 2010, tonnes	Disposed of in 2010, t/y	Landfill, t/y	Waste incineration, t/y	Hazardous waste incineration, t/y
Rubber	8,911	1126 - Conveyor belts 114 - Gaskets and hoses 14 - Production	841	412	
Sealants and adhesives	<8,000	412 – End products 12 - Processing	284	140	
Paints	<5,220	290 – End products 30 - Application	215	106	
Textile	358	23 – End products 30 - Application	16	8	3
Total	<22,489	2,024	1,356	666	3

The concentration of SCCPs in materials and in articles and the disposal methods for the different SCCP-containing wastes in Denmark are shown in Table 18. The data are, in the absence of historical data on the consumption of SCCPs in Denmark, roughly estimated on the basis of the figures for the EU as further described in the notes to the table.

The total quantity of SCCPs in the Danish waste stream is estimated at less than 7 t/y based on the results of the assessment undertaken from the European Commission (ESWI, 2011). As mentioned above, they may be underestimated because some building materials used before 1994 may still be present in the building sector. The majority of the SCCPs waste quantities are present in paint and sealant waste, accounting for almost 80 % of SCCPs in the waste stream.

If the quantities accumulated in society in Denmark today *per capita* resemble the EU average in 2010, the total quantity of SCCPs accumulated in society would be < 225 tonnes; of this < 132 tonnes would be in sealants, adhesives and paints. Of the <132 tonnes, a significant portion would be accumulated in buildings and construction. Compared to the estimated total remaining quantities of PCB in building materials of 17-87 tonnes (Grontmij and COWI, 2013), the total quantities of SCCPs may be of the same magnitude or even higher.

The concentration limit of SCCPs (CAS No. 85535-84-8) in waste to renter it hazardous is 1.0 %, due to the classification of SCCPs as a Carc. Cat. 3; R40 substance in accordance with table 3.2. of the CLP Regulation (=Carc. 2, H351 of table 3.1). Thus, some of the articles containing SCCPs are to be considered hazardous waste when disposed of. This includes rubber and textiles, and to some extent paint and sealant, if segregated from construction waste.

The disposal method depends on the actual uses of the different materials as indicated in the table. As mentioned, waste containing more than 1% SCCPs should be disposed of as hazardous waste.

So far, specific analyses of SCCPs in materials by renovations and demolition of buildings are limited and the SCCPs are mainly analysed together with PCBs in buildings from the period 1950-1977. Data have been obtained from one laboratory. During the period June-December 2013 the Danish laboratory Dansk Miljøanalyse analysed 665 samples of sealants, paints and double-glazed window seals for chlorinated paraffins (Kampmann, 2014). The samples were typically delivered for simultaneous analyses of PCBs and CPs and originate predominantly from buildings from the PCB-period stretching from 1950 to 1977. Of the 665 samples, CPs above the detection limit of 0.1 mg/kg for each substance group were demonstrated in 220 samples (33% of the analysed samples). SCCPs were the most common of the CPs and were demonstrated in 19% of the samples, whereas MCCPs and LCCPs were demonstrated in 13% and 0.5% of samples, respectively. The data indicate that SCCPs were extensively used in building materials already before 1977.

Data on the actual quantities disposed of as hazardous waste are not available.

TABLE 18
DISPOSAL OF SCCPS AND IN POST-CONSUMER WASTE IN DENMARK

Product group	Concentration in materials, %	Potential quantities of SCCP, t/y *2	Disposal method in Denmark
Rubber – mainly gaskets and hoses	10-17	1.1 *1	Landfill as waste from shredders: Rubber in vehicles (may be incinerated in the future) Incineration: Other applications
Sealants and adhesives	10-20	2.5	Incineration: Sealants and adhesives attached to combustible waste Material recovery if not segregated from demolition waste(adhesives and sealants on concrete and tile) Hazardous waste incineration: Materials identified as part of the management of double-glazed windows, demolition and renovation of buildings
Paints	1-20	2.9	Incineration: Paints on combustible materials Metal recycling: Paints on metal surfaces Material recovery if not segregated from demolition waste: Paints on concrete and tile
Textile *4	20	0.2	Landfill as waste from shredders: Textile in vehicles (may be incinerated in the future) Incineration
Leather	2	0	Incineration
Total		6.6	

*1 Calculated from the EU figures for gaskets and hoses. SCCP-containing conveyer belts for mining operations are not used in Denmark.

*2 Extrapolated from ESWI, 2011 assuming that the historic consumption in Denmark has been similar to the rest of the EU and that Denmark represent 1 % of the total EU consumption (based on population size).

*3 36 % of SCCPs is used for packaging, 36 % of other products and the remaining for wood working, transportation and consumer goods.

*4 Typical applications potentially included furniture upholstery, seating upholstery in transport applications, and interior textiles such as blinds and curtains as well as industrial protective clothing.

The Norwegian Environmental authorities examined waste containing SCCPs and MCCPs in 2010 and the proposed initiatives were published in the Norwegian Public Statement “A Norway without Environmental Poisons” (Norway, 2010).

In Norway, SCCPs and MCCPs have been detected in sealant in double-glazed windows produced between 1976-1986 (Wormstand *et al.*, 2009). A survey conducted in Norway in 2009 regarding the extension of producers’ responsibility collection schemes proposed to include double-glazed windows with sealant containing SCCPs and MCCPs within the producers’ responsibility collection scheme for double-glazed windows containing PCB (Wormstand *et al.*, 2009). The producers’ responsibility collection scheme for double-glazed windows containing PCB includes double-glazed windows produced in Norway during 1965-1975 and imported windows produced up to 1979. A collection scheme for double-glazed windows containing SCCPs and MCCPs in sealant was introduced in Norway in 2011; the waste quantities are reported separately in the national waste statistics. The declared quantities for 2011 were 179 tonnes waste, mainly in double-glazed windows (Hovde *et al.*, 2012).

The Norwegian building code lays down requirements for preparation of a waste management plan and description of environmental rehabilitation for reconstruction and demolition works in the case that SCCPs and MCCPs have been identified. See chapter 2.1.3 for more information in relation to the Norwegian legislative requirements. Building materials indicated as possibly containing SCCPs and MCCPs in Norway are the same as mentioned for Denmark in this and the next sections.

4.2.2 MCCPs in waste in the EU and Denmark

The quantity of MCCP-containing waste is considerably higher than the SCCP-containing waste, both in Denmark and the EU. The majority of MCCPs is found in flexible PVC products and accounts for more than 60% of MCCP-containing waste. The total quantity of MCCP-containing waste in Denmark is estimated to be less than 500 t/y (Table 19).

MCCP-containing waste, which originates from paints, coatings, adhesives etc. might end up in incineration plants or in demolition waste if not segregated from the relevant materials (asphalt or concrete, etc.) during demolition.

The majority of the MCCP-containing waste is likely to be incinerated or landfilled.

The Danish Statutory Order on waste (BEK nr 1309 of 18/12/2012) requires that municipalities establish systems for collection of PVC waste. PVC waste that cannot be recycled (the majority of flexible PVC) should be landfilled.

Only one MCCP (CAS No. 85535-85-9) has a harmonised classification in accordance with the CLP Regulation (attributed the r-sentences R64, R66 and R50-53). R64 and R66 are not included in waste classification. R50-53 is included, but no concentration limit has been established for this category in the EU Waste Directive or the Danish Statutory Order on waste (BEK nr 1309 of 18/12/2012, annex 4). Limit values can be applied at municipal level.

It should be noted that to render the waste as being hazardous, the concentration limits for MCCPs in waste in Norway has been set to the same as for SCCPs, i.e. 0.25 % or 2,500 mg/kg. This factor is of importance for the focus in Norway on MCCPs in waste.

TABLE 19
DISPOSAL OF MCCPS IN POST-CONSUMER WASTE IN DENMARK

Product group	Concentration in materials, %	Concentration in Article, %	Potential quantities of MCCPs in waste t/y 2*	Disposal method in Denmark
Articles with PVC	6-10% *1	6-10% in most articles (hoses, flooring, foils, etc.) Less in some articles where the PVC takes up only a part 1-5% in cables	350-450 *2	Landfilled: Main part of the larger PVC articles (e.g. hoses, flooring and wall covering) Incineration: Smaller articles of PVC or where the PVC only takes up a part of the articles (e.g. foils, textiles, furniture and smaller parts with PVC) Landfill of shredder fluff: PVC in vehicles Possibly recycling from recovery of waste cables
Articles with rubber	3-20%	3-20%	5-35 *3	Landfill of shredder fluff: Rubber in vehicles Incineration: Other applications
Paints/coatings, adhesives and sealants	1-5%	Usually used in buildings and construction	30-100 *4	Incineration: main part of sealants Material recovery or landfilled if not segregated from demolition waste
Leather	0.3-1 %	0.1-1 %	5-20 *5	Incineration

*1 Added as 10-15 parts per hundred resin corresponding to 6-10% in final material (Lassen *et al.*, 2010)

*2 From 1994 to 2006 the consumption in the EU has been relatively steady with a decrease from 45,000 t/y in 1994 to 35,000 t/y in 2006 (Entec 2007). It is roughly assumed that the consumption in Denmark during these periods corresponded to 1% of EU consumption and that the quantities in waste today equal the annual consumption during this period.

*3 From 1994 to 2006 the consumption in the EU has been relatively steady with an increase from 2,500 t/y in 1994 to 7,000 t/y in 2006 (Entec 2007). A major portion was used for the mining sector; for this portion, the consumption in Denmark would be small. It is roughly assumed that the consumption in Denmark during these periods corresponded to 0.2-0.5% of EU consumption and that the quantities in waste today equal the annual consumption during this period.

*4 The EU consumption for these mixtures has increased from 3,000 t/y in 1994 to 11,000 t/y in 2006 (Entec 2007). It is roughly assumed that the consumption in Denmark during these periods corresponded to 1% of EU consumption and that the quantities in waste today equal the annual consumption during this period.

*5 Same as above – EU consumption decreased from 1,600 to 700 t/y during this period.

4.2.3 Danish projections of CPs in waste from buildings and construction

Trap *et al.* (2006) prepared projections of the quantities of chlorinated paraffins (CPs) in waste from buildings and construction in Denmark. The study addressed the CPs collectively but indicated in some tables and figures that the data concerned SCCPs.

The projections were based on Bach *et al.* (1994) in which, however, the data is indicated to represent CAS No. 63449-39-8. Today this CAS number is used for long-chain chlorinated paraffins, but Bach *et al.* mentions that this CAS number is the only one registered in the Product Register and apparently used jointly for all CPs. Trap *et al.* (2006) assumed that the CPs had been used during the period 1960 to 2000 and assumed a life-time of 30 years for adhesives, sealants and fillers, 25 years for plastics (PVC) and 20 years for paints.

According to Bach *et al.* (1994) the consumption of the CPs in 1994 was as shown in the following table. These data from the Product Register include substances and mixtures used in both manufacturing processes and end-uses of mixtures.

TABLE 20
APPLICATIONS OF CPs IN DENMARK IN 1992 AS REGISTERED IN THE PRODUCT REGISTER (BACH *ET AL.*, 1994)

Application	Consumption in tonnes	Percentage of total
Paint	426	64%
Metal working fluids and extreme pressure additives	85	13%
Floor covering *1	18	3%
Fillers	38	6%
Flame retardants	45	7%
Softeners	45	7%
Lubricants	3	0.5%
Adhesives	2	0.3%
Binders	1	0.2%
Other	3	0.5%
Total	666	100%

*1 presumably PVC

The projection of the quantities disposed of annually is shown in Figure 7. According to the projections, about 500 t/y should be disposed of around 2014, which is in accordance with the figures estimated in **TABLE 19**.

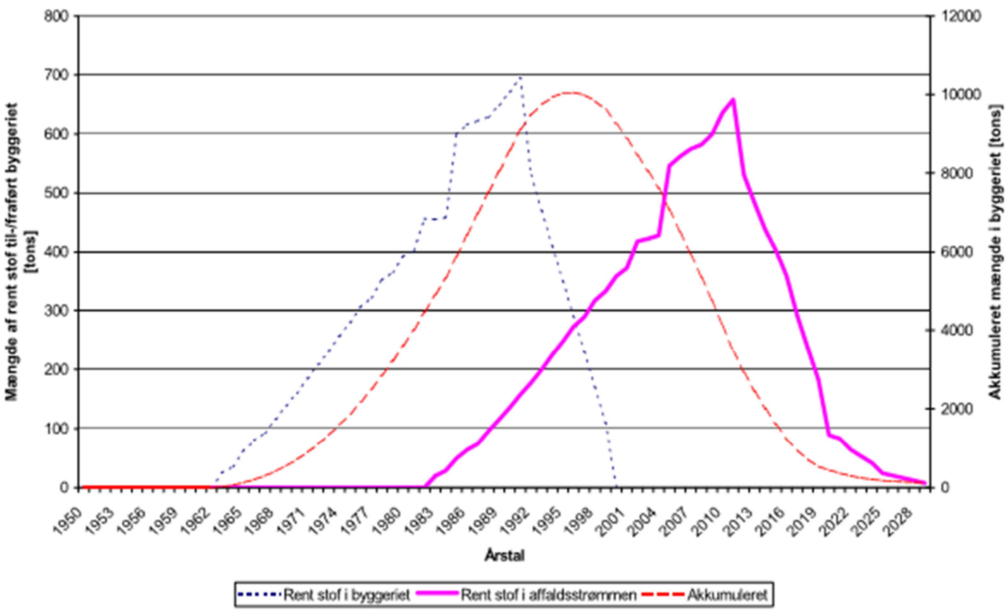

FIGURE 7
USE OF CHLORINATED PARAFFINS IN DENMARK (DOTTED LINE), ACCUMULATED QUANTITIES (DASHED LINE) AND QUANTITIES DISPOSED OFF (SOLID LINE). LEFT Y-AXIS SHOWS THE QUANTITES USED AND DISPOSED OF IN TONS, WHILE THE RIGHT X-AXIS SHOWS THE QUANTITIES ACCUMULATED IN SOCIETY

4.2.4 Danish waste legislation relevant for waste containing SCCPs and MCCPs

The previous sections make reference to Danish waste legislation relevant for waste containing SCCPs and MCCPs, whereas this section provides an overview across the two substance groups.

Hazardous waste

The EU Waste Framework Directive (Directive 2008/98/EC) and the Danish statutory order on waste (BEK nr 1309 of 18/12/2012) defines hazardous waste as waste which displays one or more of the hazardous properties listed in Annex III to the Directive and Annex IV to the statutory order.

According to the Danish Statutory Order on waste, attribution of the hazardous properties ‘toxic’ (and ‘very toxic’), ‘harmful’, ‘corrosive’, ‘irritant’, ‘carcinogenic’, ‘toxic to reproduction’, ‘mutagenic’ and ‘eco-toxic’ is made on the basis of the harmonised classification of the substances according to CLP Regulation Table 3.2.: "The list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC)". This Statutory Order establishes limit values for all of the above-mentioned hazardous properties except for substances classified “ecotoxic”.

SCCPs - The concentration limit of SCCPs (CAS No 85535-84-8) in waste to renter it hazardous is 1.0 % due to the classification of SCCPs as Carc. Cat. 3 substances (=Carc. 2, H351 of table 3.1 of the CLP Regulation).

MCCPs - One MCCP (CAS No. 85535-85-9) has a harmonised classification in accordance with the CLP Regulation, Table 3.2 as R64 (=lact, H362 in CLP, table 3.1), R66 (not translated) and R50-53 (=Aquatic Acute 1, H400 and Aquatic Chronic 1, H410 in CLP table 3.1). The hazardous properties "May cause harm to breast-fed babies" (R64) and "Repeated exposure may cause skin dryness or cracking" (R66) are not among the hazardous properties listed in Annex IV to the Danish statutory order on waste. The classification R51/53 "Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment" are among the properties which may render the waste hazardous, but the Danish statutory order on waste does not establish a limit value. This means that it is the responsibility of the municipalities to determine whether the MCCP-containing waste should be managed as hazardous waste. For assessment of the hazardous properties, the statutory order on waste makes reference to the CLP Regulation.

A search on the internet reveals that some municipalities specifically mention that only waste with more than 0.1% SCCPs are considered hazardous waste, whereas at least one municipality considers all waste with more than 0.1% of chlorinated paraffins (all CPs) to be hazardous waste (according to its website). No overview of differences between the municipalities has been identified.

Double-glazed windows
According to the Danish Statutory Order on waste, double-glazed windows should always be separately collected for possible recycling or recovery. Double-glazed windows not suitable for recycling or recovery should be destroyed or landfilled depending on the presence of hazardous substances.

PVC
According to the Danish Statutory Order on waste, the municipalities shall establish systems for collection of PVC waste - both recyclable and non-recyclable. The non-recyclable PVC (the fraction which may contain MCCPs) should be landfilled in order to reduce the quantities of PVC incinerated.

4.3 Recycling and material recovery

Based on data presented in Table 18 and Table 19, it is anticipated that only a small part of the waste containing SCCPs and MCCPs would be involved in recycling operations in Denmark.

Recycling where the intention is to recycle the materials with the CPs and retain the function of the substances has not been identified. Recycling schemes for PVC (e.g. the Wuppi system) concern recycling of rigid PVC.

PVC-sheathing of cables may be downcycled by the recovery of the cables and used for e.g. road signs. Plinke *et al.* (2000) states that generally the PVC in the sheathing is used by plastics processors, e.g. for the extrusion or injection moulding of plastics products, on the basis of an assessment of PVC cable recycling in a number of EU Member States. Data on the actual fate of the PVC by recycling of cables in Denmark today has not been investigated.

SCCP and MCCP-containing waste such as sealants, road stripes and paints might end up in demolition waste (concrete) if not correctly segregated and the demolition waste might be submitted to material recovery, mainly in road construction. Concentrations of SCCPs in the waste of 1 % or higher render the waste hazardous, and such waste should be managed as hazardous waste.

4.4 Release of SCCPs and MCCPs and degradation products from waste disposal

4.4.1 Municipal solid waste incineration

Data on emissions of SCCPs and MCCPs from incineration plants in Denmark have not been identified.

During controlled thermal treatment in municipal solid waste incinerators, the waste is incinerated at temperatures of 850-950˚C. The generated flue gases are treated to reduce the amounts of hazardous substances before they are emitted to the atmosphere. Since SCCPs and MCCPs decompose at temperatures above 200 °C (Bolliger and Randegger-Vollrath, 2003), the majority of SCCPs in the waste is therefore decomposed during incineration. Emissions of SCCPs from incineration plants are expected to be negligible, but the chloride from the SCCPs and MCCPs may be identified in several of the waste streams from waste incineration plants (PE Europe, 2010).

Hovde *et al.* (2012) quote a German study where cable waste (PVC) with 6.8 kg CPs was mixed with ordinary municipal solid waste and incinerated in a municipal solid waste incineration plant in Hamburg. The mass balance established by the study confirmed that the CPs were totally destroyed by the incineration.

As with any other chlorine-containing substances in the waste, the CPs may act as chlorine donors for post-combustion *de-novo* synthesis of dioxins and furans, PCBs and PCNs in the incinerators. Since this formation is a well-known problem with incineration, Danish incinerators have equipment for prevention of formation and releases of dioxins, furans and other POPs.

4.4.2 Releases from landfills

No data are available in the Danish landfill leachate database regarding analyses of SCCPs and MCCPs in leachate from Danish landfills.

Only few samples have been analysed, but several studies confirm the presence of SCCPs and MCCPs in leachate from landfills. In Norway, Schlabach *et al.* (2002) found SCCPs in sediments of leachate systems from landfills in 6 of 6 studied landfills in concentrations of 0.3 to 19.4 mg/kg (in each of the landfills, SCCPs were found above the detection level in one out of two samples). MCCPs were found in the sediments of 2 of the 6 landfills in concentrations of 2.7 to 11.4 mg/kg. The concentration in the leachate was not analysed, but the releases from the landfills were estimated to be in the range of 1-10 kg/year from each.

A Canadian study (Environment Canada, 2008) indicates that leaching of SCCPs and MCCPs from landfills is likely to be negligible owing to the strong binding of CPs to soils.

In a study for the Nordic Council of Ministers, the concentration of SCCPs in leachate from landfill in Norway was reported (Harstad *et al.*, 2006). The concentrations detected are shown in Table 21.

TABLE 21
SCCPS IN LANDFILL LEACHATE IN NORWAY, 2003-2004. (DATA FROM HARSTAD, 2006)

Parameter	Number of samples	Median µg/l	Min µg/l	Max µg/l
SCCP	19	339	64	614

4.4.3 SCCPs and MCCPs in wastewater and sewage sludge

In Denmark, the inlet water to two sewage treatment plants was sampled and analysed for different hazardous substances (Fredskilde and Nielsen, 2007). The results for SCCPs and MCCPs are given in Table 22. The analyses show that the concentration of the SCCPs in the inlet to the two sewage treatment plants was lower than the detection limit, whereas the concentration of the MCCPs ranged from 0.5-1.4 µg/l.

The Annual Average Ecological Quality Standards for SCCPs for inland waters are 0.4 µg/l; this may be translated into a limit value for discharges to sewer of 8 µg/l (DHI, 2007).

TABLE 22
SCCPS AND MCCPS INLET SAMPLES FROM SEWAGE TREATMENT PLANTS IN DENMARK (DHI, 2007)

Substance	Concentration in inlet waters (µg/l)	
	Weekdays	Weekend
SCCP	<0.13	<0.13
MCCP	0.5 - 1.4	0.79 - 0.81

Due to their low water solubility as well as the high Kow value, SCCPs and MCCPs accumulate in sediments and in sludge. In sewage treatment plants it is expected that about 90-93% of SCCPs and MCCPs end up in sewage sludge (Bolliger and Randegger- Vollrath 2003 as cited by COHIBA, 2011).

Data on SCCPs and MCCPs in sewage sludge in Denmark have not been identified, but some data may exist in municipalities.

In Norway, the effluent water and sludge from eight sewage treatment plants were sampled and analysed for micropollutants, including SCCPs and MCCPs (Thomas *et al.*, 2011). The results are given in Table 23.

SCCPs were detected in 65% of the effluent samples with a median concentration of 102 ng/l. SCCPs were detected in all sludge samples with a median of 0.4 mg/kg. Thomas *et al.* (2011) states that the concentrations of SCCPs in effluent and sludge are similar to those previously reported in 2008 in Norway.

MCCPs were only detected in 13 % of the effluent samples analysed. These samples contained concentrations between 170 and 942 ng/l. MCCPs were detected in all sludge samples with a median concentration of 385 ng/l (Thomas *et al.*, 2011).

The concentration of MCCPs in effluent is also similar to those reported in 2007 and 2008 in Norway, with a similar level of occurrence. Median levels reported in 2008 in Norwegian sewage sludge range from between 0.5 and 5.7 mg/kg with a maximum of 11.8 mg/kg, indicating a downward trend.

Thomas *et al.* (2011) concludes that the data suggest little or no risk to various environmental compartments from the levels determined when compared with relevant PNEC[2] data.

TABLE 23
SCCPS AND MCCPS IN SEWAGE TREATMENT PLAN SLUDGE AND EFFLUENT SAMPLES IN NORWAY (THOMAS *ET AL.*, 2011)

Substance	Concentration in sludge (mg/kg)		Concentration n effluent (ng/l)	
	Median	Range (Min. – Max.)	Median	Range (Min. – Max.)
SCCP	0.416	0.074 – 12.258	<LOD	<LOD – 560
MCCP	0.385	0.014 – 7.000	<LOD	<LOD – 942

4.5 Summary and conclusions

SCCPs - Waste with more than 1.0% SCCPs shall be managed as hazardous waste according to the Danish statutory order on waste. Materials with an intentional content of SCCPs would typically contain more than one percent of the substance, and would consequently be considered hazardous waste at end of life. Even though the use of SCCPs is restricted, materials with SCCPs are accumulated in society and may be disposed of as waste over the coming years. The main SCCP-containing materials accumulated in society and present in the waste stream are expected to be rubber, sealants and adhesives (e.g. in double-glazed windows), paints and textiles. The concentration of SCCPs in the materials renders it hazardous waste, but actual analyses of SCCPs in materials during renovation and demolition of buildings are uncommon at present. Whereas the use of PCBs continued until 1977, the use of SCCPs has continued until very recently.

[2] Predicted No-Effect Concentration

The Norwegian Environmental Authorities have initiated separate collection of double-glazed windows containing SCCPs and MCCPs in conjunction with the collection scheme for PCB-containing windows. Furthermore, in accordance with Norwegian legislation, SCCPs and MCCPs are included in the obligatory surveys of hazardous substances by renovation and demolition of buildings, and quantities of CP-containing waste are reported separately in the national waste statistics.

It is anticipated that some construction and demolition waste containing SCCPs (paints and sealants) may be used for material recovery. This process may cause an impact on the environment.

MCCPs - The presence of MCCPs in materials does not render any waste hazardous according to Danish legislation. The total quantity of MCCPs in the waste is estimated at up to 500 t/y; i.e. an estimated 10-100 times higher than the quantities of SCCPs in the waste. The main waste categories are articles containing PVC (including cables), rubber products, paints/coatings, adhesives and sealants.

The majority of the waste is estimated to be incinerated in municipal solid waste incinerators. Both SCCPs and MCCPs are nearly 100% destroyed by the incineration and not expected to act as precursors for the formation of dioxins and furans. As with any other chlorine-containing substances, they may act as chlorine donors for post-combustion *de-novo* synthesis of dioxins and furans in the incinerators, but Danish incinerators have equipment for prevention of formation and releases of dioxins and furans.

Waste water and sewage sludge - Limited data are available regarding SCCPs and MCCPs in Danish municipal sewage treatment plants. In analyses from two municipal sewage treatment plants, the SCCP concentration was below the detection limit, while the MCCP concentration ranged from 500 to 810 ng/l. Analyses of CPs in sewage sludge in Denmark have not been identified. Median levels of MCCPs reported in 2008 in Norwegian sewage sludge ranged between 0.5 and 5.7 mg/kg with a maximum of 11.8 mg/kg indicating a downwards trend. In the Norwegian assessment it was concluded that the data suggest little or no risk to various environmental compartments from the levels determined when compared with relevant toxicity data.

Data gaps

Data on the actual presence of SCCPs and MCCPs in building materials in Denmark are limited.

Data on SCCPs in outlets of from municipal sewage treatment plants and outlets from areas with separate stormwater sewers are limited.

5. Environmental hazards and exposure

5.1 Environmental hazard

5.1.1 Classification

The harmonised classification of the substances is shown in the table below.

TABLE 24
SCCPS AND MCCPS ASSIGNED ENVIRONMENTAL HAZARD CLASS AND CATEGORY CODE(S) ACCORDING TO THE CLP REGULATION

CAS No	Substance name	Environmental Hazard Class and Category Code(s)	Environmental Hazard Statement Codes
85535-85-9	alkanes, C 14-17, chloro; chlorinated paraffins, C 14-17	Aquatic Acute 1 Aquatic Chronic 1	H400 H410
85535-84-8	alkanes, C 10-13, chloro; chlorinated paraffins, C 10-13	Aquatic Acute 1 Aquatic Chronic 1	H400 H410

5.1.2 SCCPs

The environmental effects of short-chain chlorinated paraffins (SCCPs) have been extensively reviewed and evaluated previously (ECB, 2000 and 2008; ECHA, 2008b; Brooke and Crookes, 2011). The available data, taken from these reviews, are summarised in Table 25.

SCCPs are multi-constituent substances with variable and often unknown composition. The substances have relatively low water solubilities (around 0.15 to 0.47 mg/l (ECB, 2000)); the water solubility of the constituents is likely to vary with both carbon chain length and chlorine content. In most cases the ecotoxicity of SCCPs has been determined using commercial products or similar multi-constituent products. These factors mean that the interpretation of some of the ecotoxicity data for SCCPs is difficult. In particular, several studies have shown apparent toxic effects at concentrations that are orders of magnitude above the water solubility of the test substance, and the actual concentrations the organisms were exposed to may have been lower than suggested by the reported result; for example, not all of the SCCPs may have been in true solution. There is also some evidence from MCCPs that, for *Daphnia magna* in particular, physical effects (e.g. floating in the surface film) may occur when tested at concentrations in excess of the substances' solubility in the test medium. Studies where no toxicity was seen at concentrations in excess of the water solubility of the test substance are best interpreted in terms of the substance showing no toxicity at the limit of solubility in the test medium.

Overall it can be concluded that SCCPs are of generally low acute toxicity to fish. Acute toxicity tests with aquatic invertebrates have generally shown toxic effects to occur at, or close to, the water solubility of the test substance. For algae, ninety-six hour EC50s range from 0.043 to 3.7 mg/l with the marine alga *Skeletonema costatum* appearing to be more sensitive to short chain length paraffins than the freshwater alga. However, the toxic effects seen with the marine alga were transient, with no effects being seen at any concentration after 7 days exposure (ECB, 2000). The explanation for these transient effects is unclear but they could, for example, reflect a significant reduction of the exposure concentration occurring with time as a result of adsorption onto the alga (resulting in an opportunity for the algal population to recover).

Toxicity of SCCPs has also been demonstrated in fish and invertebrates following long-term exposure. The most sensitive species in long-term tests is *Daphnia magna* with a 21-day NOEC of 0.005 mg/l. The available data also show that the sensitivity of marine species is generally similar to freshwater species.

No toxicity data are available for SCCPs with sediment-dwelling organisms, but toxicity has been demonstrated in soil organisms at concentrations, generally of the order of several hundred to thousands of mg/kg dry weight. The relatively high concentrations needed to show toxicity in soils probably reflect the high adsorption of the substance to soil.

Toxicity data are also available for SCCPs for birds. The most relevant study for SCCPs is a NOAEL of 166 mg/kg diet from a reproduction study using mallard ducks (*Anas platyrhynchos*). The lowest level seen to cause slight effects in this study was 1,000 mg/kg food (ECB, 2000).

Based on the available ecotoxicity data SCCPs have been shown to meet the REACH Annex XIII criteria for toxic (T) classification as the long-term NOEC is <0.01 mg/l (ECHA, 2008a).

TABLE 25
SUMMARY OF ECOTOXICITY DATA FOR SCCPS

Trophic level	Species	Endpoint	SCCPs	Concentration	Reference *1
Water					
Freshwater fish	*Ictalurus punctatus*	96h-LC50	C10-12, 58% Cl	>300 mg/l *3	Howard *et al.*, 1975 (from ECB, 2000)
	Lepomis macrochirus	96h-LC50	C10-12, 58% Cl	>300 mg/l *3	Howard *et al.*, 1975 (from ECB, 2000)
	Leuciscus idus	48h toxic threshold	C10-13, 52% Cl	>500 mg/l *3	Hoechst, 1977 (from ECB, 2000)
			C10-13, 56% Cl	>500 mg/l *3	Hoechst, 1977 (from ECB, 2000)
			C10-13, 58% Cl	>500 mg/l *3	Hoechst, 1977 (from ECB, 2000)
			C10-13, 62% Cl	>500 mg/l *3	Hoechst, 1977 (from ECB, 2000)
			C10-13, 70% Cl	>500 mg/l *3	Hoechst, 1977 (from ECB, 2000)
	Pimephales promelas	96h-LC50	C10-12, 58% wt Cl	>100 mg/l *3	Howard *et al.*, 1975 (from ECB, 2000)
	Oncorhynchus mykiss	96h-LC50	C10-12, 58% Cl	>300 mg/l *3	Howard *et al.*, 1975 (from ECB, 2000)
		15-20d-NOEC	C10-12, 58% Cl	<0.040 mg/l	Howard *et al.*, 1975 (from ECB, 2000)
		60d-LC50	C10-12, 58% Cl	0.34 mg/l	Madeley and Maddock, 1983a (from ECB, 2000)
		168d-NOEC	C10-12, 58% Cl	≥0.017 mg/l	Madeley and Maddock (1983c) (from ECHA, 2008b)
	Oryzias latipes (embryos)	20d-NOEC	$C_{11}H_{18.4}Cl_{5.6}$ 56.9% Cl	0.057 mg/l	Fisk *et al.*, 1999 (from ECB, 2008)
		20d-NOEC	$C_{12}H_{19.5}Cl_{6.5}$ 58.5% Cl	0.0096 mg/l	Fisk *et al.*, 1999 (from ECB, 2008)
		20d-NOEC	$C_{10}H_{15.5}Cl_{6.5}$ 63.0% Cl	0.062 mg/l	Fisk *et al.*, 1999 (from ECB, 2008)

Trophic level	Species	Endpoint	SCCPs	Concentration	Reference *1
		20d-NOEC	C10H15.3Cl6.7 63.7% Cl	0.050 mg/l	Fisk *et al.*, 1999 (from ECB, 2008)
Saltwater/ estuarine fish	*Alburnus alburnus*	96h-LC50	C10-13, 49% Cl	>5,000 mg/l *3	Lindén *et al.*, 1979 (from ECB, 2000)
			C10-13, 56% Cl	>10,000 mg/l *3	Lindén *et al.*, 1979 (from ECB, 2000)
			C10-13, 63% Cl	>5,000 mg/l *3	Lindén *et al.*, 1979 (from ECB, 2000)
			C11.5, 70% Cl	>10,000 mg/l *3	Lindén *et al.*, 1979 (from ECB, 2000)
			C10-13, 71% Cl	>5,000 mg/l *3	Lindén *et al.*, 1979 (from ECB, 2000)
		14d-Behavioural effects (limit test)	C10-13, 49% Cl	0.125 mg/l	Bengtsson *et al.* 1979 (from Brooke and Crookes, 2011)
			C10-13, 59% Cl	0.125 mg/l	Bengtsson *et al.* 1979 (from Brooke and Crookes, 2011)
			C10-13, 71% Cl	0.125 mg/l	Bengtsson *et al.* 1979 (from Brooke and Crookes, 2011)
	Cyprinodon variegatus	32d-NOEC	C10-12, 58% Cl	0.28 mg/l	Hill and Maddock, 1983b (from ECB, 2000)
Freshwater invertebrates	*Caenorhabditis elegans*	48h-LC50	C10-13, 64% Cl	0.5 mg/l *2	Sochová *et al.*, 2007 (from Brooke and Crookes, 2011)
	Chironomus tentans	48h-NOEC	C10-12, 58% Cl	≥0.162 mg/l	E & G Bionomics, 1983 (from ECB, 2000)
		49d-NOEC	C10-12, 58% Cl	0.061 mg/l	E & G Bionomics, 1983 (from ECB, 2000)
	Daphnia magna	24h-EC50	C10-13, 56% Cl	0.44 mg/l to 11 mg/l *2	Huels AG, 1984 (from ECB, 2000)
			C10-12, 58% Cl	1.9 mg/l *2	Huels AG, 1984 (from ECB, 2000)
			C10-13, 60% Cl	0.51 mg/l to 4 mg/l *2	Huels AG, 1984 (from ECB, 2000)
			C10-13, 61% Cl	0.3 mg/l to 3 mg/l *2	Huels AG, 1984 (from ECB, 2000)
		48h-EC50	C10-13, 56% Cl	0.138 mg/l	Frank and Steinhäuser, 1994 (from ECB, 2008)
			C10-13, 56% Cl	0.14 mg/l	Koh and Thiemann, 2001 (from ECB, 2008)
			C10-12, 58% Cl	0.53 mg/l *2	Thompson and Madeley, 1983a (from ECB, 2000)
			C10-13, 62% Cl	0.075 mg/l	Koh and Thiemann, 2001 (from ECB, 2008)
		72h-EC50	C10-12, 58% Cl	0.024 mg/l	Thompson and Madeley, 1983a (from ECB, 2000)
		96h-EC50	C10-12, 58% Cl	0.018 mg/l	Thompson and Madeley, 1983a (from ECB, 2000)
		5d-EC50	C10-12, 58% Cl	0.014 mg/l	Thompson and Madeley, 1983a (from ECB, 2000)
		21d-NOEC	C10-13, 20% Cl	0.05 mg/l	Huels AG, 1986 (from ECB, 2000)

Trophic level	Species	Endpoint	SCCPs	Concentration	Reference *1
			C10-13, 56% Cl	0.05 mg/l	Huels AG, 1984 (from ECB, 2000)
			C10-12, 58% Cl	0.005 mg/l	Thompson and Madeley, 1983a (from ECB, 2000)
			C10-13, 60% Cl	<0.050 mg/l	Huels AG, 1986 (from ECB, 2000)
			C10-13, 61% Cl	0.02 mg/l	Huels AG, 1986 (from ECB, 2000)
		21d-EC0	C10-12, 58% Cl	0.03 mg/l	Huels AG, 1986 (from ECB, 2000)
Saltwater invertebrates	*Mysidopsis bahia*	96h-LC50	C10-12, 58% Cl	0.014 mg/l	Thompson and Madeley, 1983d (from ECB, 2000)
		28d-NOEC	C10-12, 58% Cl	0.007 mg/l	Thompson and Madeley, 1983d (from ECB, 2000)
	Mytilus edulis	60d-NOEC	C10-12, 58% Cl	0.044 mg/l	Madeley and Thompson, 1983 (from Brooke and Crookes, 2011)
		60d-LC50	C10-12, 58% Cl	0.074 mg/l	Madeley and Thompson, 1983 (from ECB, 2000)
		12 weeks - effects on growth	C10-12, 58% Cl	0.0093 mg/l	Thompson and Shillabeer, 1983 (from ECB, 2000)
	Nitrocra spinipes	96h-EC50	C10-13, 70% Cl	<0.3 mg/l *2	Tarkpea *et al.*, 1981 (from ECB, 2008)
Freshwater algae	*Scenedesmus subspicatus*	72h-NOEC	C10-13, 56% Cl	≥0.2 mg/l	Koh and Thiemann, 2001 (from ECB, 2008)
			C10-13, 62% Cl	≥0.1 mg/l	Koh and Thiemann, 2001 (from ECB, 2008)
	Pseudokirchneriella subcapitata	96h-EC50	C10-12, 58% Cl	3.7 mg/l *2	Thompson and Madeley, 1983b (from ECB, 2000)
Saltwater algae	*Skeletonema costatum*	96h-EC50	C10-12, 58% Cl	0.043 mg/l	Thompson and Madeley, 1983c (from ECB, 2000)
		96h-NOEC	C10-12, 58% Cl	0.012 mg/l	Thompson and Madeley, 1983c (from ECB, 2000)
Sediment					
No data					
Soil and terrestrial environment					
Terrestrial invertebrates	*Caenorhabditis elegans*	48h-NOEC	C10-13, 64% Cl	1,000 mg/kg dry soil	Bezchlebová *et al.*, 2007 (from Brooke and Crookes, 2011)
		48h-LC50	C10-13, 64% Cl	8,836 mg/kg dry soil	Bezchlebová *et al.*, 2007 (from Brooke and Crookes, 2011)
	Eisenia fetida	28d-NOEC	C10-13, 64% Cl	1,000 mg/kg dry soil	Bezchlebová *et al.*, 2007 (from Brooke and Crookes, 2011)
	Enchytraeus albidus	42d-NOEC	C10-13, 64% Cl	3,000 mg/kg dry soil	Bezchlebová *et al.*, 2007 (from Brooke and Crookes, 2011)
	Enchytraeus crypticus	21d-NOEC	C10-13, 60% Cl	≥1,000 mg.kg dry soil	Sverdrup *et al.*, 2005 (from Brooke and Crookes, 2011)
		28d-NOEC	C10-13, 64% Cl	6,000 mg/kg dry soil	Bezchlebová *et al.*, 2007 (from Brooke and Crookes, 2011)
	Folsomia candida	28d-EC10	C10-13, 64% Cl	600 mg/kg dry	Bezchlebová *et al.*, 2007 (from

Trophic level	Species	Endpoint	SCCPs	Concentration	Reference *1
				soil	Brooke and Crookes, 2011)
Soil microorganisms	Respiration (CO_2) inhibition	28d-NOEC	C10-13, 64% Cl	5,000 mg/kg dry soil	Bezchlebová *et al.*, 2007 (from Brooke and Crookes, 2011)
	Nitrogen transformation	28d-NOEC	C10-13, 60% Cl	300 mg/kg dry soil	Sverdrup *et al.*, 2005 (from Brooke and Crookes, 2011)
Terrestrial plants	*Trifolium pratense*	21d-NOEC	C10-13, 60% Cl	≥1,000 mg/kg dry soil	Sverdrup *et al.*, 2005 (from Brooke and Crookes, 2011)

*1 See ECB (2000 and 2008) and UNEP (2011) for full reference.

*2 Value above the water solubility of the substance. These data are difficult to interpret as the actual dissolved concentration the organisms were exposed to is unclear.

*3 Value highly above the water solubility of the substance. As in these tests little or no effects were seen, then these data are best interpreted as showing no effects at the solubility limit of the test substance.

The PNECs derived for SCCPs in ECB (2000 and 2008) are summarised in Table 3.

TABLE 26
SUMMARY OF PNECS DERIVED FOR SCCPS AND MCCPS (ECB, 2000, 2005, 2007 AND 2008)

Substance	PNEC		
	Freshwater	Sediment	Soil
SCCPs	0.5 µg/l	2.2 mg/kg wet sediment	1.8 mg/kg wet soil
MCCPs	1 µg/l	5 mg/kg wet sediment	10.6 mg/kg wet soil

5.1.3 MCCPs

The environmental effects of medium-chain chlorinated paraffins (MCCPs) have been extensively reviewed and evaluated previously (ECB, 2005 and 2007; Brooke and Crookes, 2011). The available data, taken from these reviews, are summarised in Table 27.

Similar to SCCPs, MCCPs are multi-constituent substances with variable and often unknown composition and with low water solubilities (around 0.005-0.027 mg/l (ECB, 2005)). Therefore, the interpretation of the ecotoxicity data presents similar problems as those seen for SCCPs (and there is some evidence for physical effects in *Daphnia magna* such as floating in the surface film following exposure to relatively high concentrations (above around 0.35 mg/l) of MCCPs (ECB, 2005)). For MCCPs, toxicity has been demonstrated in aquatic organisms, mainly in *Daphnia magna* following short-term and long-term exposure. The 21d-NOEC for *Daphnia magna* is around 0.010 mg/l (ECB, 2005).

No toxicity has generally been seen in the available short-term experiments with fish. Effects were seen on algal biomass and growth but only at concentrations above the solubility of the substance. The results of 60-day tests are available with fish and mussels but both of these used test concentrations significantly higher than the solubility of the substance. Fish showed no effects on mortality, growth or behaviour at 1 and 4.5 mg/l, but mussels showed some effect on filtration rate and the NOEC was taken as 0.22 mg/l. The toxicological significance of this latter result is unclear as the effect concentrations reported are above the water solubility of the substance; therefore, the possibility of direct ingestion of undissolved (or sorbed) test substance by the filter feeding organisms cannot be ruled out. Similarly no effects were seen in a 20 day embryo-larval test with fish.

Overall the available data with aquatic species show that *Daphnia magna* is the most sensitive species to MCCPs. There is a potential discrepancy between the acute toxicity data for *Daphnia magna* and the results obtained in longer-term studies. For example a 48h-EC50 of 0.0059 mg/l has been determined in one study, which is lower than the long-term NOEC of around 0.010 mg/l. The exact reason for this discrepancy is unknown but possible explanations were considered in ECB

(2005), possibly related to the lack of feeding in the acute tests making the organisms more sensitive to toxic effects than in longer-term tests, where feeding is carried out.

The toxicity of MCCPs has been determined in both sediment and soil organisms. For sediments, the most sensitive species tested were *Hyalella azteca* and *Lumbriculus variegatus*, both of which resulted in a 28d-NOEC of 130 mg/kg dry sediment. For soil, the most sensitive species tested was *Eisenia fetida* which had a 56d-NOEC of 280 mg/kg dry soil.

Toxicity data are also available for MCCPs with birds (ECB, 2005). No mortality or abnormal symptoms have been seen in either mallard duck (*Anas platyrhynchos*) or ring-necked pheasant (*Phasanius colchius*) following a single oral dose of a C14-17, 52% chlorinated paraffin of 10,280 mg/kg body weight (mallard duck) or 24,606 mg/kg body weight (ring-necked pheasant) or following dietary exposure for 5 days to doses up to 24,063 mg/kg feed. Though a slight depression of food intake occurred at the latter level for mallard duck, no significant effects on weight gain were noted.

The status of MCCPs with regard to the REACH Annex XIII criterion for toxic (T) classification has been considered in ECB (2005 and 2007). Although the long-term NOEC for *Daphnia magna* of 0.01 mg/l sits on the cut-off for the T-criterion it was thought that, on balance, the T-criterion was met as there are a number of other data for *Daphnia magna* close to (and in one case just below) this value, and effects have been seen in *Daphnia magna* at concentrations <0.01 mg/l in an acute study. However, it was also recognised that there is little information on how the toxicity of MCCPs varies with chlorine content (and carbon chain length); this is an important consideration for the PBT assessment of MCCPs (see below).

The PNECs derived for MCCPs in ECB (2005) are summarised in Table 3.

TABLE 27
SUMMARY OF ECOTOXICITY DATA FOR MCCPS

Trophic level	Species	Endpoint	MCCPs	Concentration	Reference *1
Water					
Freshwater fish	*Leuciscus idus*	48h toxic threshold	C14-17, 41% Cl	400 mg/l *2	Hoechst AG, 1976 (from ECB, 2005)
			C14-17, 41% Cl*	>500 mg/l *3	Hoechst AG, 1977 (from ECB, 2005)
			C14-17, 49% Cl	>500 mg/l *3	Hoechst AG, 1977 (from ECB, 2005)
	Oncorhynchus mykiss	60d-NOEC	C14-17, 52% Cl,	≥4.5 mg/l *3	Madeley *et al.*, 1983b (from ECB, 2005)
	Oryzias latipes (embryos)	20d-NOEC	C14H24.9Cl5.1, 48% Cl	≥3.4 mg/l *3	Fisk *et al.*, 1999 (from ECB, 2005)
		20d-NOEC	C14H23.3Cl6.7, 55% Cl	≥1.6 mg/l *3	Fisk *et al.*, 1999 (from ECB, 2005)
Saltwater/ estuarine fish	*Alburnus alburnus*	96h-LC50	C15.5, 40% Cl	>5,000 mg/l *3	Lindén *et al.*, 1979 (from ECB, 2005)
			C14-17, 50% Cl	>5,000 mg/l *3	Lindén *et al.*, 1979 (from ECB, 2005)
			C14-17, 52% Cl	>10,000 mg/l *3	Lindén *et al.*, 1979 (from ECB, 2005)
		14d-NOEC	C14-17, 50% Cl	≥0.125 mg/l *3	Bengtsson *et al.* 1979 (from ECB, 2005)

Trophic level	Species	Endpoint	MCCPs	Concentration	Reference *1
Freshwater invertebrates	*Daphnia magna*	48h-EC50	C14-17, 52% Cl	0.0059 mg/l	Thompson *et al.*, 1996 (from ECB, 2005)
		21d-NOEC	C14-17, 52% Cl	0.010 mg/l	Thompson *et al.*, 1997b (from ECB, 2005)
			C14-17, 52% Cl	0.013-0.016 mg/l	Frank and Steinhäuser, 1994 (from ECB, 2005)
			C14-17, 52% Cl	approx. 0.004-0.008 mg/l	TNO, 1993 (from ECB, 2005)
	Gammarus pulex	96h-LC50	C14-17, 52% Cl	> 1.0 mg/l *3	Thompson and Gore, 1999 (from ECB, 2005)
Saltwater invertebrates	*Nitrocra spinipes*	96h-LC50	C14-17, 45% Cl	9 mg/l *2	Tarkpea *et al.*, 1981 (from ECB, 2005)
			C14-17, 52% Cl	>10,000 mg/l *3	Tarkpea *et al.*, 1981 (from ECB, 2005)
	Mytilus edulis	60d-NOEC	C14-17, 52% Cl,	0.22 mg/l *2	Madeley and Thompson, 1983 (from ECB, 2005)
Freshwater algae	*Pseudokirchneriella subcapitata*	72h-NOEC	C14-17, 52% Cl	0.1 mg/l *2	Thompson *et al.*, 1997a (from ECB, 2005)
		72h-EC50	C14-17, 52% Cl	>3.2 mg/l *2	Thompson *et al.*, 1997a (from ECB, 2005)
Sediment					
Freshwater sediment invertebrates	*Chironomus riparius*	28d-NOEC	C14-17, 52% Cl	3,800 mg/kg dry sediment	Thompson *et al.*, 2001c (from ECB, 2005)
	Hyalella azteca	28d-NOEC	C14-17, 52.5% Cl	130 mg/kg dry sediment	Thompson *et al.*, 2002 (from ECB, 2005)
	Lumbriculus variegatus	28d-NOEC	C14-17, 52% Cl	130 mg/kg dry sediment	Thompson *et al.*, 2001d (from ECB, 2005)
Soil and terrestrial environment					
Terrestrial invertebrates	*Eisenia fetida*	56d-NOEC	C14-17, 52.5% Cl	280 mg/kg dry soil	Thompson *et al.*, 2001b (from ECB, 2005)
Soil microorganisms	Nitrogen transformation	28d-NOEC	C14-17, 52.5% Cl	≥400 mg/kg dry soil	Thompson, 2002 (from ECB, 2005)
Terrestrial plants	*Brassica napus*	21d-NOEC	C14-17, 52% Cl	≥5,000 mg/kg dry soil	Thompson *et al.*, 2001a (from ECB, 2005)
	Phaseolus aureus	21d-NOEC	C14-17, 52% Cl	≥5,000 mg/kg dry soil	Thompson *et al.*, 2001a (from ECB, 2005)
	Triticum aestivum	21d-NOEC	C14-17, 52% Cl	≥5,000 mg/kg dry soil	Thompson *et al.*, 2001a (from ECB, 2005)

*1 See ECB (2005 and 2007) for full reference.

*2 Value above the water solubility of the substance. These data are difficult to interpret.

*3 Value highly above the water solubility of the substance. As in these tests no effects were seen, then these data are best interpreted as showing no effects at the solubility limit of the test substance.

5.1.4 Combined exposure and effects

As SCCPs and MCCPs (and also long-chain chlorinated paraffins, LCCPs) are structurally closely related, and in some cases have similar uses (and hence sources of release to the environment), it is possible that an organism in the environment will be exposed to several types of chlorinated paraffins simultaneously. The possibility of combined effects from such exposure has been considered in detail in UNEP (2011). It was concluded that the available data were suggestive of a common mode of action for SCCPs, MCCPs and LCCPs and that the effects from simultaneous exposure to more than one type of chlorinated paraffin are likely to be best described by an approach based on concentration (dose) addition. Based on this method, UNEP (2011) developed a quantitative approach that could be used to assess the possible effects on the environment (and on humans) from combined exposure to chlorinated paraffins. The tentative conclusions were that a) the potential for effects in surface water and sediment appear to result mainly from the combined exposure from SCCPs and MCCPs, with LCCPs generally making only a minor contribution to the toxicity predicted, and b) for predators and humans exposed via food, the analysis suggested that all three groups may make a significant contribution to the toxicity predicted.

5.2 Environmental fate

5.2.1 SCCPs

The environmental fate of SCCPs has been reviewed and evaluated in detail in ECB (2000 and 2008) and UNEP (2010). The following is a summary of the relevant information based on these evaluations.

SCCPs are expected to react in the atmosphere with hydroxyl radicals and the atmospheric half-life is estimated to be between 1.9 and 7.2 days based on this reaction (ECB, 2000).

Hydrolysis and photolysis of SCCPs are not thought to be environmentally relevant degradation processes. SCCPs have a small but measurable vapour pressure at room temperature (approximate range 0.0035-0.028 Pa at 25°C for substances with chlorine content between 45 and 52% Cl and 1.4×10-4-5.4×10-3 Pa at 25°C for substances with chlorine contents between 55 and 61% Cl; ECB, 2008). UNEP (2010) concluded that SCCPs have the potential to undergo long-range transport via the atmosphere.

The available evidence suggests that SCCPs may biodegrade slowly in the environment, particularly those with lower chlorine contents. Older laboratory studies have generally shown that SCCPs are not readily biodegradable in standard laboratory test systems, but there is evidence for biodegradation occurring in the presence of adapted microorganisms or in the presence of certain bacteria (ECB, 2000). However, many of these studies used relatively high concentrations of SCCPs (in excess of the water solubility) and so may have been compromised by limited bioavailability of the substance during the tests. More recent studies (summarised in UNEP, 2012b) where the bioavailability of the SCCPs tested had been improved have been carried out; these showed that more substantial biodegradation of a SCCP with a 50% Cl content occurs in ready biodegradation tests and that the substance met the criteria for ready biodegradation under some test conditions.

Biodegradation simulation tests have confirmed that, although biodegradation of SCCPs can occur, the half-life for ultimate biodegradation (mineralisation) in sediments is relatively long (ECB, 2008). Laboratory studies using both freshwater and marine sediments have been carried out using the OECD 308 Test Guideline with a C10, 65% Cl substance and a C13, 65% Cl substance. The biodegradation was determined under both aerobic and anaerobic conditions. The mean mineralisation half-life (average of the two substances - assumed to be representative of a C10-13, 65% wt. Cl product) under aerobic conditions was determined to be around 1,630 days in freshwater sediment and 450 days in marine sediment. Under anaerobic conditions no substantial mineralisation was evident over the course of the study. The extent of any primary degradation was not determined under either aerobic or anaerobic conditions (ECB, 2008).

High bioconcentration factors (BCFs) have been measured for SCCPs in fish and molluscs. Whole body BCFs up to 7,816 l/kg (fish) and 40,900 l/kg (molluscs) have been determined. Uptake into fish via diet has also been demonstrated with accumulation factors between around 1 and 2 being determined (on a lipid basis) in feeding studies (ECB, 2000 and 2008). Biomagnification factors (BMFs) above 1 have been determined for SCCPs in some food webs (UNEP, 2012b).

Monitoring data have shown that SCCPs are present in a range of aquatic organisms in the environment including fish and marine mammals. Although some of the data relate to samples collected near to industrial sources, SCCPs have also been found in wildlife from more remote locations, including samples from the Arctic. The concentrations reported range up to a few mg/kg (ECB, 2008).

SCCPs have high log Kow values (approximate range 4.5 to 8.5) and so are expected to adsorb strongly onto sediment and soil in the environment.

5.2.2 MCCPs

The environmental fate of MCCPs has been reviewed previously in ECB (2005 and 2007) and the following summary is based mainly on these reviews. MCCPs are listed on the Community Rolling Action Plan and are currently undergoing a substance evaluation under REACH[3]. However, the results of the substance evaluation are not currently publicly available.

The atmospheric half-life of MCCPs is estimated to be around 1-2 days based on the reaction with hydroxyl radicals.

Hydrolysis and photolysis are not thought to be important degradation process for MCCPs in the environment (ECB, 2005). MCCPs have a small but measurable vapour pressure at room temperature (2.27×10^{-3} Pa at 40°C for a substance with 45% chlorine content and 2.7×10^{-4} Pa at 20°C for a substance with 52% chlorine content; ECB, 2005). ECB (2007) considered the potential of MCCPs for long-range transport. This concluded that the potential for transport was lower than that for SCCPs, but that the possibility of long range transport could not be completely ruled out.

Similar to the case with SCCPs, biodegradation of MCCPs has been demonstrated in laboratory studies but it is thought that the potential for degradation decreases with increasing chlorine content (ECB, 2007). Recent tests (unpublished reports summarised in the registration dossier in the ECHA dissemination data base) show that MCCPs with lower chlorine contents are readily biodegradable in standard test systems where the bioavailability of the MCCPs has been maximised, but that MCCPs with higher chlorine content biodegrade progressively more slowly as the chlorine content increases.

Although the laboratory studies show that MCCPs can undergo biodegradation (and in some cases can be considered to be readily biodegradable), it is not currently possible to estimate a rate constant or derive half-lives for degradation of the more highly chlorinated MCCPs in the environment.

The available data indicate that medium-chain chlorinated paraffins are taken up by organisms from water, sediment/soil and food (ECB, 2005 and 2007). The bioconcentration factor (BCF) for MCCPs in rainbow trout has been measured[4] as 1,087 l/kg for a C15-chlorinated paraffin with a chlorine content of 51% wt. and 6,600- 9,100 l/kg for a C_{14}-chlorinated paraffin with a chlorine content of 45% wt. (ECB, 2005 and 2007; Thompson and Vaughan, 2014). ECB (2007) used a modelling/read-across approach to show how the BCF is predicted to vary with both carbon chain length and chlorine content, with higher BCFs generally being predicted for shorter carbon chain lengths and lower chlorine contents.

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

[4] These studies are based on 14C-measurements; the results may therefore represent metabolites as well as the parent compound.

Biomagnification factors BMFs (determined as the growth corrected concentration in fish on a lipid weight basis/the concentration in food on a lipid weight basis) in the range 1-3 have been determined for several medium-chain chlorinated paraffins of specific carbon chain lengths[5] (ECB, 2007).

Monitoring studies have reported medium-chain chlorinated paraffins to be present in biota in the environment, including marine fish and marine mammals (top predators such as porpoise and fin whale) amongst others (EU, 2005 and 2007). Thompson and Vaughan (2014) have recently reviewed the available information on accumulation of MCCPs in the environment and concluded that although laboratory studies have shown that MCCPs can be accumulated from water and food, the available field data (albeit limited) shows that trophic magnification of MCCPs is not occurring.

MCCPs have high log Kow values (approximate range 4.5 to 8.2; ECB, 2005) and so are expected to adsorb strongly onto sediment and soil in the environment.

5.2.3 Formation of SCCPs from MCCPs and LCCPs

According to the Environmental Risk Assessment of long-chain chlorinated paraffins (LCCPs), little information is available on the possible degradation products of LCCPs (Brooke *et al.*, 2009). Of possible concern for the environment would be if the LCCPs broke down to provide the more bioavailable SCCPs and MCCPs in the environment. According to the risk assessment this possibility is unlikely to be significant.

Under aerobic conditions, the most likely mechanism for degradation would be ß-oxidation, which would lead to chain shortening by two carbon units each time, but more importantly would also lead to oxidation of the terminal carbon, usually forming an acid group. Also, such processes tend to progress step-wise down the carbon chain and there is no reason why, if degradation did occur, it would stop at a carbon chain length of C10-13. Co-metabolic degradation experiments carried out by Omori *et al.* (1987 as cited by Brooke *et al.*, 2009) indicated that ß-oxidation, to form initially chlorinated fatty acids, which are then broken down to 2- or 3-chlorinated fatty acids was the most likely degradation mechanism for chlorinated paraffins. It is unlikely that SCCPs and MCCPs themselves would be formed under such conditions from LCCPs (Brook *et al.*, 2009).

Under anaerobic conditions, most chlorinated compounds appear to degrade by reductive dechlorination, which removes chlorine from the molecule but would not be expected to alter the carbon chain length. This sort of reaction has been most extensively studied for halogenated aromatics, but substances such as tetrachloroethylene and trichloroethylene appear to degrade in a similar way (Brook *et al.*, 2009).

The considerations above regarding the degradation of LCCPs to SCCPs would also apply to the degradation of MCCPs.

5.2.4 PBT and POPs assessment

Short-chain chlorinated paraffins

SCCPs meet the REACH Annex XIII criteria for both persistence and bioaccumulation and the substance; hence, the substance has been identified as a PBT and vPvB substance (ECHA, 2008 and 2008b).

SCCPs are currently under consideration according to the criteria for persistent organic pollutants (POPs) for inclusion under the Stockholm Convention (UNEP, 2006 and 2010). No final decision

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[5] It should also be noted that the majority of the food uptake studies are based on ^{14}C-measurements, and there is some evidence that substantial metabolism may have been occurring in the organisms. This means that although radioactivity was found in the organisms, the concentrations found do not necessarily represent those of the parent compound.

has yet been reached as to their eventual status under this Convention (UNEP, 2012a). SCCPs are listed on the UNECE Protocol on Persistent Organic Pollutants (POPs) (UNECE, 2010).

Medium-chain chlorinated paraffins

The PBT-properties of MCCPs have been considered in ECB (2007) and are currently being considered under the Substance Evaluation procedure of the REACH Regulation. As noted previously, the ECB (2007) evaluations concluded that the substance meets the T-criterion. However, as MCCPs are multi-constituent substances, there are uncertainties over both the persistence and bioaccumulation potential for MCCPs and further information is needed in order to conclude on whether or not the substance meets the P or B criteria (ECB, 2007).

In particular it is important to note that the MCCPs constituents with the highest measured (or predicted) BCFs are also those that are most biodegradable. It is understood that a request for further information (further testing) on the biodegradation and bioaccumulation potential of MCCPs is being considered as a result of the recent substance evaluation of MCCPs being carried out under the REACH regulation (Medium-Chain Chlorinated Paraffins REACH Consortium).

MCCPs are not currently under consideration in relation to POPs.

5.3 Environmental exposure

5.3.1 Sources of release

Chlorinated paraffins might be released into the environment from manufacturing processes (chlorination), formulation (e.g. formulation of rubber or paints), applications and use of products, and solid waste disposal (BRE, 2008).

Releases in Denmark

No detailed assessment of releases of either SCCPs or MCCPs in Denmark is available. Based on the assessment by DCE (2010), it can be stated the SCCPs have been released to the marine environment, but data are insufficient for quantifying the releases.

Releases at EU level

SCCPs - The maximum releases to the environment of SCCPs from manufacturing sites in the EU were estimated at less than 9.9 to 26.7 kg/year for each manufacturing site. While there were four SCCP manufacturing plants in the EU in 2008, the current number has not been investigated, but is assumed to be lower due to the restricted application of SCCPs (BRE *et al.*, 2008).

The release of SCCPs has been estimated based on consumption data from 2004 for the EU25 (BRE *et al.*, 2008). The lifecycle release categories manufacture, formulation of products (rubber, sealants, paints, textile backcoatings), and use of products were estimated to be either very small (< 0.1 t/y) or negligible. In any case, those releases are no longer relevant due to the restrictions on manufacture and use of SCCPs.

More substantial releases originate from SCCPs in articles (rubber goods, building materials, textiles, articles with paints and/or coatings) and from unintentional formation during MCCP manufacture. These two sources were estimated to account for 21.4 – 44.8 t/y and < 33.4 t/y, respectively (for all environmental compartments). Since SCCP-containing articles and products are still in use, and MCCP manufacture is not restricted, those release sources do presumably still exist.

MCCPs -The releases of MCCP production and use have been estimated in the EU RAR (ECB, 2005). The estimation was based on data from 4 production sites from 2004, while a fifth plant was taken into account qualitatively. Since the consumption of MCCPs has not changed significantly since 2004, the estimated releases might still be realistic today.

Local releases from the production sites were estimated at 10^{-5} - 0.22 kg/day, resulting in regional and continual release estimates of 65 kg/year to wastewater and 37 kg/year to surface water, respectively.

Among the use sources, the use of metal cutting/working fluids accounts for the largest release to wastewater at 138.8 t/y. The total regional and continental releases are summarised in Table 28. Compared to the releases from use, the releases from production are negligible.

TABLE 28
TOTAL REGIONAL AND CONTINENTAL RELEASES OF MCCPS TO THE ENVIRONMENT (INCLUDING 'WASTE REMAINING IN THE ENVIRONMENT') (ECB, 2005)

Compartment	Estimated regional release (t/y)	Estimated continental release (t/y)
Air	17	154
Water	207 – 219	1,871 – 1,975
Urban/industrial soil	82.6 – 97.3	743 – 876

Furthermore, C17, and to a smaller extent, C16 chlorinated paraffins are present as impurities in some types of LCCP, which are likewise used in PVC applications, paints and leather fat liquors. There is also the possibility of MCCPs being released to the environment as a result of weathering/erosion of particulate materials. The EU RAR emphasizes that, in the absence of an agreed methodology on how to deal with these potential sources in the risk assessment, the environmental modelling of these releases is highly uncertain (ECB, 2005).

Based on the emission data, predicted environmental concentrations (PECs) have been calculated for each environmental compartment in the EU RAR. Since secondary poisoning through the food chain is a relevant exposure pathway for MCCPs, biota concentrations have also been predicted for fish and earthworms.

Releases in the Baltic Sea Region
The objective of the COHIBA (2012) project was to assess the release patterns and pathways into the Baltic Sea marine environment of substances of concern, as well as to quantify the inputs of the selected hazardous substances to the Baltic Sea by using and assessing models. Both SCCPs and MCCPs were included in the project.

For the Baltic Sea input modelling, six source categories were distinguished: Industry, service life, municipal sewage treatment plants, waste and sewerage, other and historic contamination.

According to the COHIBA assessment (2012), the emissions of MCCPs are about ten times higher than the emissions of SCCPs. Likewise, the number of sources identified for MCCPs is almost twice as many as identified for SCCPs. In Figure 8, a simplified substance flow analysis is shown for the combined flow of SCCPs and MCCPs, indicating that the largest deposition of chlorinated paraffins is to the land compartment.

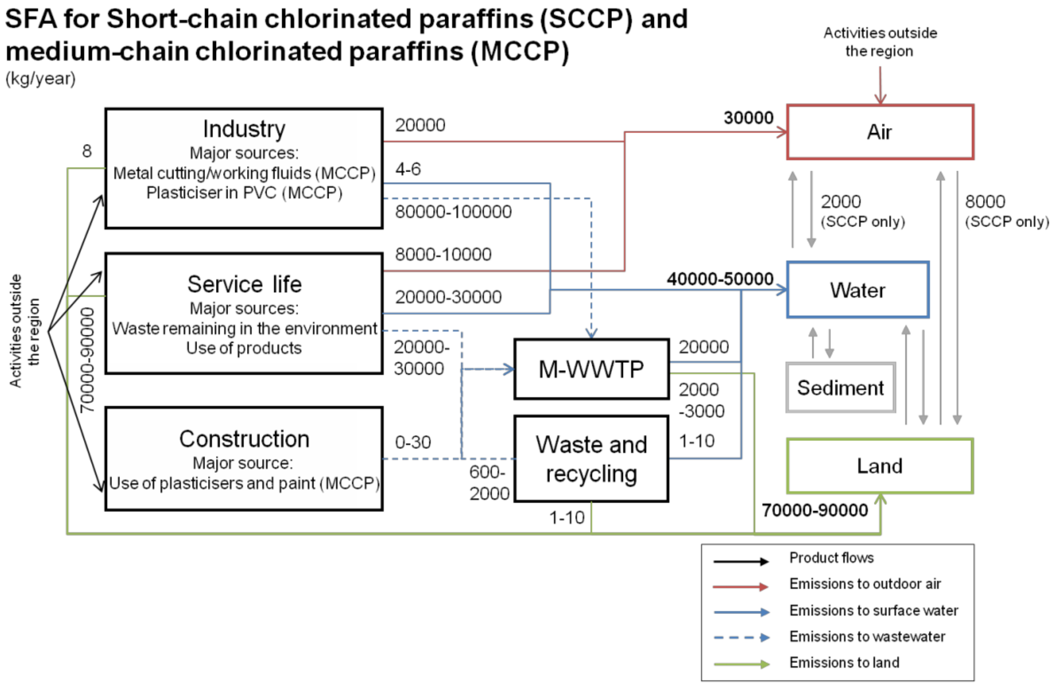

FIGURE 8

SIMPLIFIED SUBSTANCE FLOW ANALYSIS (SFA) FOR SCCPS AND MCCPS IN THE BALTIC SEA REGION (COHIBA, 2012)

For both SCCPs and MCCPs, the emissions into the Baltic environment mainly originate from service life sources. In the service life category, emissions from 'waste remaining in the environment' are the dominant source for both SCCPs and MCCPs in all countries. Waste remaining in the environment includes e.g. particulates of polymeric products, paints and sealants containing chlorinated paraffins. The second largest source was release from lifetime use of paints and PVCs.

The dominating industry source was use of MCCPs as plasticisers in the manufacture of PVC in Poland, Germany and possibly Finland, with most emissions coming from Poland. Latvia reported industrial emissions from use of MCCPs as plasticisers in the formulation of paints and varnishes. This may also be a source in Germany and Estonia.

Emissions from municipal sewage treatment plants were of importance for SCCPs and MCCPs in some of the Baltic countries. The emissions of MCCPs to wastewater primarily come from industrial sources, mainly from the use of MCCPs as an additive in metal cutting/working fluids. This source has been quantified in Finland, Poland and Sweden, and identified as a possible source in Estonia. In the service life category, volatile and leaching loss over lifetime use of products containing SCCPs and MCCPs was the main source of emissions to wastewater, but accounted for less than 10% of the total emissions to wastewater.

According to the COHIBA study, SCCPs and MCCPs in the Baltic area are mainly released to land areas and the distribution between environmental compartments does not differ very much between the low and high emission scenarios.

The total yearly load to the Baltic Sea catchment has been estimated to be higher for SCCPs and MCCPs than for any of the other selected hazardous substances. The annual emissions of SCCPs and MCCPs are about 140 – 180 tonnes.

Even though the use of SCCPs has been decreasing over the last decades, the main sources of emissions are articles that may have a long service life. Therefore, there will be a delay in the effect of reduced use on the yearly releases to the environment.

The COHIBA (2011) guidance document on emission reduction of SCCPs and MCCPs states that "*SCCP stemming from waste from the rubber industry is expected to fall by about 60% from 2010 to 2020, due to reduction of SCCP use in the production of rubber products in the past years. In case of sealants and adhesives it is estimated that in a best case the waste amount will drop by 50%, and by 75% in the case of paints and varnishes, both due to the drop of used amounts of SCCP in the last years. For textile industry amounts are expected to remain constant, while on the other hand it is expected that the waste stream from leather industry will vanish within the next 2 years, considering an average life time of 6 to 12 years.*"

Since MCCPs have similar uses as SCCPs, they might function as replacements for the SCCPs in some applications. A reduction in the use of SCCPs could therefore lead to an increased use of MCCPs. However, in Sweden the use of MCCPs has decreased since 1996. The report furthermore emphasizes the high level of uncertainty of some of the estimations for SCCP and MCCP emissions since the most significant sources, such as use of products and waste remaining in the environment, are based on very rough estimations (COHIBA, 2011).

Releases in the North Sea Region

No literature addressing emissions of chlorinated paraffins in the North Sea could be identified.

5.3.2 Monitoring data

The Danish NOVANA assessment programme

Chlorinated paraffins are not comprised by the Danish NOVANA assessment programme (NOVANA, 2011), but a screening of SCCPs and MCCPs in Danish marine and fresh water sediments has been conducted (DMU, 2010). The average concentrations of the sampling locations are shown in Table 29. MCCPs could not be detected in the sediment samples.

TABLE 29
RESULTS OF A SCREENING STUDY OF SCCPS AND MCCPS IN SEDIMENTS OF DANISH WATERS (DMU, 2010)

Substance	Sediment type	Number of samples	Average ±standard deviation (ng/g)	Year
SCCPs	Marine sediment	10	25±7	2008
SCCPs	Fresh water sediment	10	27±11	2008
MCCPs	Marine sediment	10	Not detected	2008
MCCPs	Fresh water sediment	10	Not detected	2008

In the Danish Marine Strategy's Basic Analysis, it is generally concluded that chlorinated aliphatic hydrocarbons do not occur to any significant extent in the marine environment, since several studies have shown that SCCPs occur in very low concentrations or below the detection limit in the open sea (Naturstyrelsen, 2013). MCCPs are not mentioned, but it can be assumed that the conclusion would be similar, since the water solubility of MCCPs is even lower. None the less, SCCPs have been categorised as a substance for which knowledge is lacking and which should be monitored in future in relation to the nature restoration programme at the freshwater Mølleå-system (Naturstyrelsen, 2012).

SCCPs and MCCPs in the Baltic and North Sea Region

In 2002, Sweden presented a guidance document on SCCPs under HELCOM (HELCOM, 2002a). However, since SCCPs are not in HELCOM's regular monitoring programmes, monitoring data have only been sparsely available and date mostly back to the 1980s.

More recent data are referred to in the following sections.

The German Federal Environment Agency published data on fish liver (from cod, dab, flounder) and sediment concentrations of SCCPs and MCCPs from the North and Baltic Seas collected during 2002-2004 (UBA, 2008). Furthermore, liver and muscle tissues from birds from Bear Island were sampled.

Fish liver samples from the North Atlantic (cod) from locations at Iceland, Lofot Islands and Bear Island were analysed for comparison. The results for SCCPs and MCCPs are summarised in Table 30 and Table 31, respectively.

From the data it could be concluded that tissue concentrations of chlorinated paraffins in fish liver from the North and Baltic Seas are not species-specific and levels were comparable for the North Sea and the Baltic Sea. Levels in cod liver from remote areas (Lofot Islands/Iceland) are considerably lower than in cod from the North and Baltic Seas. Generally, higher concentrations of MCCPs compared to SCCPs could be observed in fish of the Baltic and birds (for bird data, see Table 33). This difference is most pronounced in the UBA study (2009) for fish liver concentrations in the Baltic Sea, where MCCP levels exceed SCCP levels by a factor of 9.

TABLE 30
SCCPS FISH LIVER CONCENTRATIONS

Sea	No of samples	SCCP concentration		Year	Reference
		Average (ng/g wet weight)	Range (ng/g wet weight)		
Baltic Sea	97	19	19 - 408	2002-2003	UBA, 2008
North Sea	6	144	21 - 521	2002-2003	UBA, 2008
Baltic Sea	23	23	5.2 - 62	2008	IVL, 2009

TABLE 31
MCCPS FISH LIVER CONCENTRATIONS

Sea	No of samples	MCCP* concentration range		Year	Reference
		Average (ng/g wet weight)	Range (ng/g wet weight)		
Baltic Sea	97	171	25 - 1265	2002-2003	UBA, 2008
North Sea	6	220	< 10 - 893	2002-2003	UBA, 2008
Northern North Atlantic	14	19	7 - 47	2003-2004	UBA, 2008
Baltic Sea	23**	2.1	< LOD** - 15	2008	IVL, 2009

* MCCPs only quantified in the chain lengths C14-C15

** MCCPs were detected in 3 out of 23 samples

*** LOD were ranging from 0.25 – 2.8 ng/g wet weight

The results of a screening study by the Swedish Environmental Research Institute (IVL, 2009) are also given in Table 32. IVL (2009) states that they found lower levels of chlorinated paraffins in fish liver samples (herring, perch, and flounder) than in earlier studies, partly reflected by comparison with the data from UBA (2008). MCCPs could only be detected in 3 out of 23 fish samples, in lower concentrations than SCCPs. No clear regional or species differences could be identified. By comparison with other reported values, the authors recognise that the level and distribution of SCCPs and MCCPs diverge in their results from other findings (IVL, 2009).

The conclusions from both the German and Swedish studies indicate the MCCPs have a higher bioaccumulation potential than SCCPs.

In addition to fish liver samples, sediment samples have also been taken from a number of locations in the Baltic and North Seas (Table 32).There were too few samples from the single years for SCCPs and MCCPs; therefore, only the total chlorinated paraffin concentration is given in Table 32.

TABLE 32
SEDIMENT CONCENTRATIONS OF CHLORINATED PARAFFINS IN THE BALTIC SEA

Sea	No of samples	Average SCCP concentration and range (ng/g ww)	Average MCCP concentration and range (ng/g ww)	Year	Reference
Baltic Sea	7	68 (21 - 105)	117 (48 – 117)	2001	UBA, 2008
Baltic Sea	7	35 (13 – 82)	67 (36 – 141)	2004	UBA, 2008
North Sea	16	33 (5 - 112)*		2002	UBA, 2008
North Sea	16	46 (9 – 98)*		2003	UBA, 2008

* TOTAL CONCENTRATION OF CHLORINATED PARAFFINS.

Total chlorinated paraffin levels in sediments from the Baltic Sea (45-377 ng/g dw) were generally higher than in those from the North Sea (5-355 ng/g dw), but were similar when expressed on the basis of total organic carbon (TOC).

SCCPs and MCCPs in the Arctic environment
Neither SCCPs nor MCCPs are substances included in the AMAP monitoring programme.

The Danish National Centre for Environment and Energy (DCE) recently published a review of the occurrence of compounds in the Arctic which are not covered by the current monitoring activities in Greenland (Vorkamp and Rigét, 2013).

SCCPs have been detected in Arctic biota, comprising sea birds and fish from Bear Island (Svalbard Archipelago), fish from Iceland, belugas and ringed seals from the Canadian Arctic, and belugas and walrus from Greenland. SCCPs have also been detected in abiotic Arctic samples such as Arctic lake sediments and air on Bear Island.

Vorkamp and Rigét (2013) categorise SCCPs as substances with potential for biomagnification, where molecules with 4-6 Cl exhibit the greatest potential for biomagnification. Trophic magnification factors (TMFs) > 1 for food chains in two Canadian lakes have been determined. Still, SCCPs have a shorter half-life in fish than e.g. PCBs and accumulate less than other POPs.

MCCPs are likewise categorised as substances with a potential for biomagnification (Vorkamp and Rigét, 2013). The BMF of MCCPs has been shown to be < 1 for some species in Canadian lakes. Biomagnification could not be determined for certain chain lengths due to trophic dilution. As with SCCPs, MCCPs have a shorter half-life in fish than e.g. PCBs.

The Norwegian Environment Agency recently published a screening of chlorinated paraffins in polar biota and investigated biomagnification along the food chain including fish, birds, ringed seal and polar bear (NILU, 2013). The data document that higher trophic feeders have higher concentrations of chlorinated paraffins (in lipid weight, Figure 9). Differences in the pattern between species might, according to NILU (2013), be explained by the fact that MCCPs cannot be transformed to SCCPs under environmental conditions, as well as that MCCPs are less likely to be transferred in uptake processes due to higher molecular mass. The estimated BMFs result in values ranging between 2.3 for SCCPs and 2.0 for MCCPs, indicating a biomagnification potential for both substance groups.

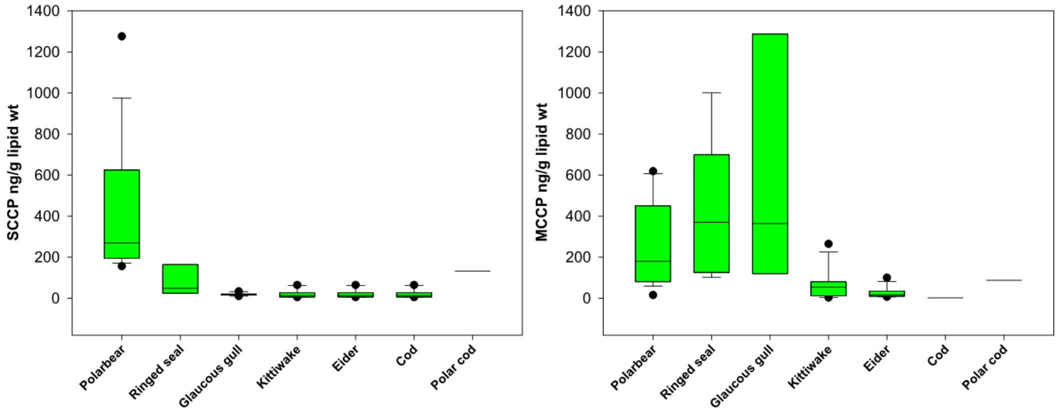

FIGURE 9

BOX PLOT OF SCCPS (LEFT) AND MCCPS (RIGHT) IN ARCTIC BIOTA. THE BOUNDARY OF THE BOX IS THE 25TH AND 75TH PERCENTILE; THE LINE MARKS THE MEDIAN, PLOT WITH ERROR BARS AND OUTLYING POINTS. LINES WITHOUT STATISTICS ARE BELOW THREE VALID DATAPOINTS (>DETECTION LIMITS) (FROM NILU, 2013).

Measured concentrations of SCCPs and MCCPs in the Arctic environment are summarised in Table 33 and 34. SCCPs and MCCPs could be detected and/or quantified in the majority of the Arctic samples (NILU 2013; UBA, 2008), indicating a widespread exposure to these chemicals in the marine Arctic.

TABLE 33
SCCP CONCENTRATIONS IN THE ARCTIC ENVIRONMENT

Location	Compartment	No. of samples *3	Concentration (range or ± standard deviation)	Unit	Year	Reference
Bear Island	Air	n.s.	1.8 - 10.6 *1	ng/m^3	2003*2	NILU 2013
St. Lawrence River, Canada	Water	n.s.	15.7 - 59.6	ng/l	2003*2	NILU 2013
Arctic lakes	Freshwater sediment	n.s.	1.6 - 257	ng/g	1997*2	NILU 2013
Arctic Ocean	Biota (Beluga whale blubber)	n.s.	1.78 - 80.0	µg/g ww	2000*2	NILU 2013
Arctic Ocean	Biota (Beluga whale liver)	n.s.	0.545 to 20.9	µg/g ww	2000*2	NILU 2013
Bear Island	Biota (Birds: Little Auk and Kittiwake)	8	24 (5 – 88)	ng/g ww	2001	UBA, 2008
Northern North Atlantic	Biota (Fish, cod liver)	14	43 (±11 – 70)	ng/g ww	2003-2004	UBA, 2008
Northern North Atlantic	Biota (Fish, cod liver)	n.s.	17 - 70	ng/g ww	2006*2	NILU 2013
Northern North Atlantic	Biota (Bird, Arctic char)	n.s.	7 -27	ng/g ww	2006*2	NILU 2013
Svalbard	Biota (Polar bear, plasma)	20	3.99 (±2.91)	ng/mL plasma	2012/2013	NILU 2013
Svalbard	Biota (Ringed seal, plasma)	10	4.96 (±2.70)	ng/mL plasma	2012/2013	NILU 2013
Svalbard	Biota (Bird, Glacous gull plasma)	12	3.95 (±1.99)	ng/mL plasma	2012/2013	NILU 2013
Svalbard	Biota (Bird, Kittiwake egg)	12	7.83 (±8.26)	ng/g ww	2012/2013	NILU 2013
Svalbard	Biota (Bird, common eider egg)	12	3.23 (±1.77)	ng/g ww	2012/2013	NILU 2013
Svalbard	Biota (Fish, Atlantic cod liver)	3	10.3 (±10.7)	ng/g ww	2012/2013	NILU 2013
Svalbard	Biota (Fish, Polar cod liver)	10	2.28 (-)	ng/g ww	2012/2013	NILU 2013

* 1 Total CP
*2 Date of original literature publishing and not of sampling year.
*3 n.s. – number of samples not specified in the reference.

TABLE 34
MCCP CONCENTRATIONS IN THE ARCTIC ENVIRONMENT

Location	Compartment	No. of samples *1	Concentration (range or ± standard deviation)	Unit	Year	Reference
Bear Island	Air	n.s.	1.8 - 10.6	ng/m³	2003*2	NILU 2013
Bear Island	Biota (Birds: Little Auk and Kittiwake)	8	73 (5 – 371) *3	ng/g ww	2001	UBA, 2008
Northern North Atlantic	Biota (Fish, cod liver)	14	24 (5 – 88) *3	ng/g ww	2003-2004	UBA, 2008
Northern North Atlantic	Biota (Fish, cod liver)	n.s.	7-47	ng/g ww	2006*2	NILU 2013
Northern North Atlantic	Biota (Bird, Arctic char)	n.s.	10 -47	ng/g ww	2006*2	NILU 2013
Svalbard	Biota (Polar bear, plasma)	20	2.20 (± 1.84)	ng/mL plasma	2012/2013	NILU 2013
Svalbard	Biota (Ringed seal, plasma)	10	2.91 (±2.39)	ng/mL plasma	2012/2013	NILU 2013
Svalbard	Biota (Bird, Glaucous gull plasma)	12	8.87 (±9.88)	ng/mL plasma	2012/2013	NILU 2013
Svalbard	Biota (Bird, Kittiwake egg)	12	4.91 (±4.88)	ng/g ww	2012/2013	NILU 2013
Svalbard	Biota (Bird, common eider egg)	12	4.24 (±4.07)	ng/g ww	2012/2013	NILU 2013
Svalbard	Biota (Fish, Atlantic cod liver)	3	0.94 (-)	ng/g ww	2012/2013	NILU 2013
Svalbard	Biota (Fish, Polar cod liver)	10	1.15 (-)	ng/g ww	2012/2013	NILU 2013

*1 n.s. – number of samples not specified in the reference.

*2 Date of original literature publishing and not of sampling year.

*3 MCCPs only quantified in the chain lengths C14-C15

SCCPs and MCCPs could be detected and/or quantified in the majority of the Arctic samples (NILU 2013; UBA, 2008), indicating a widespread exposure to these chemicals in the marine Arctic (Table 33 and Table 34).

SCCP concentrations exceeded the MCCP-levels in polar bear and ringed seal plasma, kittiwake eggs, Atlantic cod liver, and polar cod. The opposite was the case for glaucous gull plasma and eider duck eggs (NILU, 2013). Total chlorinated paraffin levels in biota decreased in the following order: Ringed Seal > Polar Bear >> Kittiwake > Glaucous Gull > Eider duck > Atlantic cod liver (on a lipid weight basis). Due to the different tissues analysed of the various species, caution has to be applied when comparing and ranking the species (NILU, 2013).

The data compilation by the UBA study (2008) also shows that birds (Little Auk and Kittiwake) from remote areas in the Northern North Atlantic can have similar concentrations of chlorinated paraffins as fish from the Baltic and the North Sea. Muscle tissue from Arctic char from the background site Bear Island (Svalbard archipelago) has comparable levels to the cod liver from the North and Baltic Seas. MCCP concentrations in birds exceed SCCPs concentrations by a factor of 1 – 4 (comparing ranges).

Generally, there is good agreement between the corresponding tissue concentrations in biota in the two studies (fish liver and bird tissue samples). Comparing concentrations in biota (fish and bird samples) over the years, there is a tendency toward lower concentration in the most recent samples. However, comparison of the data is difficult due to different analytical methods and the large natural variation of biological samples, and should therefore be interpreted with caution.

The main reasons for the exposure to chlorinated paraffins can be explained as long-range transport and condensation effects, a high precipitation rate around the sampling site, Lake Ellasjøen, and the breeding sites of thousands of sea birds close by resulting in an input via guano (UBA, 2008).

5.4 Environmental impact

It is beyond the scope of this survey to provide an environmental impact assessment. The following briefly summarises the findings of existing risk assessments or preliminary assessments prepared on the basis of monitoring data, e.g. in the context of HELCOM, OSPAR or AMAP. However, such evaluations are either not available or outdated; the following section is therefore solely based on the European risk assessments from 2000 and 2005 for SCCPs and MCCPs, respectively.

SCCPs

The environmental risks have been evaluated in the EU RAR from 2000 and led to the conclusions that there was a need for limiting the risks and for further information and/or testing for some applications (ECB, 2000). The RAR concluded that there was a need for limiting the risks to aquatic organisms arising from the local emission of SCCPs from metal working applications and leather finishing, and from the formulation of products for these uses. This conclusion also applied to secondary poisoning arising from formulation and use in leather finishing, and use in metal working applications.

Subsequently, most applications of SCCPs were restricted.

A renewed environmental risk assessment considering the changes in use of SCCPs and the newly available toxicity and monitoring data has not been performed in recent years.

SCCPs have also been raised as a possible concern with regard to long range atmospheric transport. Since 2000, several studies have been published documenting the widespread presence of SCCPs in the environment, as well as the Arctic environment, consequently confirming the concern. The significance of this is currently being discussed by the POPs Review Committee under the Stockholm Convention (POPRC, 2012).

MCCPs

The environmental impact of MCCPs is described and evaluated in the EU RAR (ECB, 2005). Since the use pattern of MCCPs has not changed considerably during the last decade, the assessment from 2005 still provides valuable information.

MCCPs have a high acute toxicity towards aquatic organisms, a high potential for bioconcentration, and are poorly degradable.

The estimated local PEC/PNEC ratios for surface water are >1 for several of the life-stages of MCCPs, indicating an existing risk. The risk to surface water from regional sources is low.

The estimated environmental risks have also led to the following conclusions in the EU RAR (ECB, 2005):
"There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account."

This conclusion applies to the following compartments;

For surface water, a risk is identified from the following applications:

- Use in the production of PVC in some processes (particularly where compounding or compounding and conversion is carried out in partially open systems).
- Formulation of metal cutting fluids, and use in emulsifiable metal cutting/working fluids where the spent fluid is discharged to wastewater.
- Use in leather fat liquors.

For sediment, a risk is identified from the following applications:

- Use in PVC:
  - plastisol coating
  - extrusion/other compounding and conversion sites using partially open processes or sites carrying out both compounding and conversion using open, partially open or closed processes.
- Use in plastics/rubber: sites carrying out conversion or both compounding and conversion.
- Use in metal cutting/working fluids:
  - formulation sites
  - use in oil-based fluids at large and small sites.
  - use in emulsifiable fluids at sites with intermittent release (disposal) to sewer/drain.
- Use in leather fat liquors: use at sites carrying out processing of hides/leather.
- Use in carbonless copy paper: sites carrying out paper recycling.

For the terrestrial compartment, a risk is identified from:

- Use in PVC: extrusion/other - sites carrying out both compounding and conversion using partially open systems.
- Use in metal cutting/working fluids:
  - formulation sites.
  - use in emulsifiable fluids at sites with intermittent release (disposal) to sewer/drain.
- Use in leather fat liquors: use at sites carrying out processing of hides/leather.
- Regional assessment of "waste remaining in the environment".

For secondary poisoning, a risk is identified from all uses of MCCPs for the earthworm food chain (other than for production (sites where there is no spreading of sewage sludge to land), formulation and use of sealants, and domestic application of paints). The following scenarios also indicate a concern for the fish food chain:

- Production sites.
- Use in the production of PVC:
  - plastisol coating.
  - extrusion/other.
- Use in the production of plastic/rubber.
- Formulation of paints and industrial application of paints.
- Formulation and use in metal cutting/working fluids (all types).
- Formulation and use in leather fat liquors.
- Recycling of carbonless copy paper.

5.5 Summary and conclusions

Environmental fate and effects

Both SCCPs and MCCPs are multi-constituent substances with variable and often unknown composition, with relatively low water solubilities and high log Kow values. This means that the interpretation of much of the environmental fate and effects data is complicated, and the properties will vary with factors such as carbon chain length and chlorine content.

Aquatic invertebrates (in particular *Daphnia magna*) appear to be a sensitive group in terms of aquatic toxicity of both SCCPs and MCCPs. The long-term NOEC for *Daphnia magna* has been determined as 0.005 mg/l for SCCPs and 0.010 mg/l for MCCPs. Toxicity to sediment-dwelling organisms has also been demonstrated for MCCPs (no data are available for SCCPs) and both SCCPs and MCCPs have been shown to cause effects in soil organisms, but only at concentrations of the order of hundreds to thousands of mg/kg dry weight. Combined effects resulting from simultaneous exposure of organisms to both SCCPs and MCCPs are predicted to occur.

SCCPs and MCCPs are expected to be degraded in the atmosphere by reaction with hydroxyl radicals (half-life 1.9-7.2 days for SCCPs and 1-2 days for MCCPs). Both SCCPs and MCCPs have the potential for long-range transport via the atmosphere but the potential for transport of MCCPs is thought to be lower than that for SCCPs.

The available evidence suggests that both SCCPs and MCCPs can undergo biodegradation but that the rate of biodegradation may decrease with increasing chlorine content.

It is considered unlikely that LCCPs and MCCPs are degraded in the environment to shorter-chained chlorinated paraffins.

Uptake and accumulation in fish from both water and food has been demonstrated in laboratory studies for both SCCPs and MCCPs; BCFs of up to 7,800 and 6,600 l/kg have been measured for SCCPs and MCCPs respectively. The BCF is expected to vary depending on the carbon chain length and chlorine content, generally decreasing as chain length and chlorine increase. Both SCCPs and MCCPs have been detected in a range of aquatic organisms in the environment, including marine mammals. There is evidence of biomagnifcation of SCCPs in some food webs.

Both SCCPs and MCCPs are predicted to adsorb strongly to sediment and soil in the environment.

SCCPs have been shown to meet the REACH Annex XIII criteria for both a PBT and a vPvB substance and are currently under consideration according to the criteria for POPs for inclusion under the Stockholm Convention. The PBT and vPvB status of MCCPs under REACH is still under discussion.

Releases to the environment

CPs are released into the environment from manufacturing processes, formulation (e.g. formulation of rubber or paints), applications and use of products (mainly via wastewater), and solid waste disposal.

An assessment of environmental releases of neither SCCPs nor MCCPs in Denmark is available, but has been performed in the context of the European Risk Assessment Reports (EU RAR) for the two substance groups and for the Baltic Sea Region.

The releases to the Baltic Sea Region have been assessed for the 7 countries of the Baltic Sea region. The annual emissions of SCCPs and MCCPs are about 140 – 180 t/y. The emissions of MCCPs are about ten times higher than the emissions of SCCPs and the main receiving compartment is land rather than the water and air compartments.

For both SCCPs and MCCPs, the emissions into the Baltic environment mainly originate from products in service and the waste phase, including emissions from 'waste remaining in the environment' (e.g. particulates of polymeric products, paints and sealants containing chlorinated paraffins) release from lifetime use of paints and PVC. The dominating industry sources of MCCPs were use of MCCPs as plasticisers in the manufacture of PVC and in formulation of paints and varnishes. The main sources of SCCP emissions are articles that may have a long service life. Therefore, there will be a delay in the effect of reduced use on the yearly releases to the environment.

Emissions from municipal sewage treatment plants were of importance for SCCPs and MCCPs in some countries.

Monitoring data – levels in the environment
Chlorinated paraffins are not encompassed by the Danish NOVANA assessment programme, but a single screening study of Danish marine and fresh water sediments could detect SCCPs, not MCCPs, in the sediment samples. A considerable number of monitoring data of tissues from fish, birds, and Arctic mammals, as well as sediment concentrations, are available for the Baltic and North Sea regions as well as for the Arctic environment.

The total level of chlorinated paraffins in sediments from the Baltic Sea were generally higher than in those from the North Sea, but were similar when expressed on the basis of total organic carbon (TOC). A few sediment samples from the North Sea showed that MCCPs concentrations were about twice the concentration of SCCPs.

SCCPs have also been detected in Arctic sediment samples. Tissue concentrations of chlorinated paraffins in fish liver from the North and Baltic Seas are not species-specific and levels were comparable for the North Sea and the Baltic Sea. Fish liver concentrations from remote marine areas appear to be considerably lower than samples from the North and Baltic Seas.

MCCPs and SCCPs are categorised as substances with potential for biomagnification. Generally, higher concentrations of MCCPs compared to SCCPs are found in fish tissues of the Baltic and North Seas, probably due to higher releases.

With respects to Arctic biota, SCCPs and MCCPs could be detected and/or quantified in the majority of the Arctic samples, indicating a widespread exposure to these chemicals in the marine Arctic.

Trophic magnification factors have been estimated for the Arctic food chain and resulted in values of about 2.3 for SCCPs and 2.0 for MCCPs, indicating a biomagnification potential for both substance groups, even though differences in the concentration pattern in the Arctic species between SCCPs and MCCPs were found.

SCCPs have been detected in Arctic air. Long-range transport and condensation effects have been mentioned as being among the main reasons for exposure of Arctic biota to chlorinated paraffins.

Environmental impact
The EU RAR on SCCPs from 2000 concluded that there was a need for limiting the risks to aquatic organisms from these chemicals. Subsequently, most applications of SCCPs have been restricted.

The significance of long-range atmospheric transport of SCCPs is currently being discussed by the POPs Review Committee under the Stockholm Convention (POPRC, 2012).

The EU RAR from 2005 on MCCPs states that the substances have a high acute toxicity towards aquatic organisms, a high potential for bioconcentration, and are poorly degradable. The risk ratios (PEC/PNEC) exceeded 1 for several compartments, especially in the local scenarios, while no risks were identified in most of the regional scenarios.

Assessments of the risks of the SCCPs and MCCPs in the Danish, Baltic Sea and North Sea environments have not been identified.

Data gaps

Several studies report difficulties in quantifying chlorinated paraffins, leading to uncertain concentrations in the different environmental media. Furthermore, neither SCCPs nor MCCPs are integrated in a regular monitoring programme. Therefore, spatial and temporal comparisons of study results are fraught with uncertainty and do not allow for distinct conclusions about historical development of environmental concentrations or effects of control measures. Consistent future monitoring data might reveal to what extent the recent restriction on use and production of SCCPs influences environmental concentrations. Furthermore, it may be regarded as important to follow the development of environmental concentrations of MCCPs, since they might substitute for SCCPs in certain applications.

The PBT-properties of MCCPs are currently being considered under the Substance Evaluation procedure of the REACH Regulation. As MCCPs are multi-constituent substances, there are uncertainties over both the persistence and bioaccumulation potential for MCCPs and further information is needed in order to conclude on whether or not the substance meets the P or B criteria.

The significance of long-range transport of SCCPs and MCCPs is still under debate.

6. Human health effects and exposure

6.1 Human health hazard

6.1.1 Classification

The harmonised health hazard classifications of SCCPs and MCCPs are shown in Table 35. SCCPs are suspected of causing cancer in humans, while MCCPs may cause harm to breast-fed children, as indicated by their health classification.

TABLE 35
HEALTH HAZARD CLASSIFICATION ACCORDING TO REGULATION (EC) NO 1272/2008 (CLP REGULATION)

Index No	International Chemical Identification	CAS No	Classification	
			Hazard Class and Category Code(s)	Hazard statement Code(s) *
602-080-00-8	alkanes, C 10-13, chloro; chlorinated paraffins, C 10-13	85535-84-8	Carc. 2	H351
602-095-00-X	alkanes, C 14-17, chloro; chlorinated paraffins, C 14-17	85535-85-9	Lact.	H362

* Hazard statement codes: H351: Suspected of causing cancer, H362: May cause harm to breast-fed children.

6.1.2 Short-chain chlorinated paraffins

Health effects are described in the European Risk Assessment report (EU RAR; ECB, 2000) and newer evaluations are included in the SVHC support document from 2008 (ECHA, 2008). Furthermore, an evaluation of health hazards of chlorinated paraffins for the proposal of a health-based quality criterion for ambient air has recently been published by the Danish EPA (Nielsen and Ladefoged, 2013).

Toxicokinetics and metabolism

In general, there is very limited information on the toxicokinetics of SCCPs. Additionally, information with respect to the influence of chain length and chlorination degree on absorption is limited.

No information on the toxicokinetics of SCCPs following inhalation or dermal exposure in animals is available in the referenced sources. In an *in vitro* study exposing human skin to SCCPs with 56 %-chlorination, less than 0.01 % of the applied dose was absorbed during 56 hours' contact (ECB, 2000). The only information on absorption of SCCPs in humans is from an *in vitro* study which demonstrated extremely poor absorption across skin samples. As well, the physicochemical properties and information on longer chained chlorinated paraffins indicate that dermal absorption is minimal.

Nielsen and Ladefoged (2013) reviewed the toxicokinetics based on several authoritative reports, i.e. ECB (2000), WHO (1996), and IARC (1990). Absorption, distribution and excretion have been investigated in a study with C57B1 mice treated (single dose by gavage) with ^{14}C-labelled SCCPs (C12) with a chlorination degrees of 17.5%, 55.9% and 68.5%. Uptake of radioactivity 24 hours after administration (whole-body autoradiography) was highest in tissues with high metabolic activity and/or high rates of cell proliferation, e.g. intestinal mucosa, bone marrow, brown fat, salivary glands, thymus and liver. The accumulation of radioactivity appeared to increase with increasing degree of chlorination. Twelve hours after administration of the SCCP with 55.9%-chlorination, 62% was recovered, with 33% as CO_2 in exhaled air, 29% in urine, and 5% in faeces. After administration of SCCP with 68.5%-chlorination, only 33% was recovered with 8% as CO_2 in exhaled air, 4% in urine, and 21% in faeces. The 17.5%-chlorinated SCCPs were not investigated in this part of the study.

In another study, F344 rats were treated daily with 10 or 625 mg/kg bw/day of SCCPs (C10-12, chlorination degree of 58%) in the diet for 13 weeks. After 13 weeks, all animals as well as groups of animals that were not pre-treated received a single oral (gavage) dose of ^{14}C-labelled SCCPs, same dose level as received daily in the previous weeks. Tissue levels were proportional to the administered dose and were similar, irrespective of dosing regime. The highest initial concentrations of radioactivity were found in the liver, kidney, adipose tissue and ovaries. Approximately 54-66% of the radioactivity was recovered in the faeces in 7 days, 14% in the urine, and less than 1% in exhaled air (CO_2) (Nielsen and Ladefoged, 2013).

Both studies demonstrated a significant absorption following oral administration and distribution to tissues with high metabolic activity and/or high rates of cell proliferation. Results from the study with mice administered a single dose of SCCPs indicated a higher absorption for the SCCPs with lower chlorination states. Excretion of SCCPs and/or their metabolites occurs via faeces, urine and exhaled air.

No attempts have been made to identify any metabolites, although cytochrome P450 oxidation to CO_2 has been demonstrated (ECB, 2000).

Acute toxicity
No information is available on the effects of acute exposure to SCCPs in humans. The limited information available from animal studies clearly demonstrates that SCCPs are of very low acute toxicity, with no toxicity occurring in rats following 1-hour exposure to a vapour or aerosol of 3300 mg/m^3 or with a dermal dose of 2.8 g/kg. Some signs of systemic toxicity were observed with oral doses of up to 13 g/kg C_{10-13} chlorinated paraffin, 40 to 70 % chlorinated (containing up to 5% epoxy stabilisers with various additives) in rats and up to 27 g/kg C_{12},, 60 % chlorinated, in mice. Signs of toxicity included piloerection, urinary incontinence and lethargy. A very high, unsubstantiated dermal LD50 of approximately 13.5 g/kg (C_{12}, 59 % chlorinated) has been reported in rabbits. The nature and degree of effects have been found to be independent of degree of chlorination.

Irritation and sensitization
Limited information in humans indicates that SCCPs do not cause skin irritation. A number of animal studies with rabbits and rats support this information. Two well-conducted skin irritation studies in animals indicate that SCCPs with a chlorination degree of 59 and 70% have the potential to produce, at most, minimal skin irritation. Several unpublished studies indicate that more pronounced irritation can occur following repeated dermal exposure to SCCPs. This has been demonstrated to be independent of chain length and chlorination degree and is probably due to a defatting action.

There is no information on the potential of SCCPs to cause eye irritation in humans. However, the information from animals indicates that SCCPs produce only mild eye irritation in rabbits.

No conclusions can be drawn from the limited information available on skin sensitisation in humans. The absence of reports on skin sensitisation, despite the widespread use of these substances, is suggested as an indication that SCCPs do not have the potential to be skin sensitizers. This conclusion is supported by negative results from two well-conducted, respected skin sensitisation studies in animals exposed to C10-13, 50 and 56% chlorinated paraffin. There are no data concerning the effects of varying chain length or chlorination degrees.

No direct information is available on respiratory sensitisation in animals or humans. Again, the widespread use of these industrially important substances and the absence of any case reports suggest that SCCPs do not as act respiratory sensitizers.

Sub-chronic and chronic toxicity
There is no information available on the effects of repeated exposure to SCCPs either in humans or on standard inhalation or dermal studies in animals. All available oral studies in animals were conducted using SCCPs with a chlorination degree of 52 to 60%, which does not allow the drawing of conclusions on the toxicity related to different degrees of chlorination.

The liver, thyroid and kidney have been identified as target organs following oral administration to rats and mice. Observed increases in liver weight are likely to be due to a physiological response to the demand for xenobiotic metabolism or peroxisome proliferation. Larger increases in liver weight and hepatocellular hypertrophy have been shown to be a reflection of peroxisome proliferation. Humans are not susceptible to peroxisome proliferation and hence the liver effects are not considered relevant to human health.

Increases in thyroid weight and follicular cell hypertrophy have been shown to be caused by stimulation of the thyroid via a negative feedback mechanism, initiated by increased excretion and plasma depletion of the T4-thyroid hormone. The depletion of T4 is a result of increased liver enzyme activity (UDPG-transferase) which may be related to peroxisome proliferation. Humans and rodents show different T4-globulin binding characteristics, meaning that humans are less susceptible to plasma T4 depletion and hence to thyroid stimulation (consult section on Mechanisms and interactions for further explanation on the negative feedback mechanism). Overall, the thyroid effects seen in rats and mice are considered unlikely to be relevant to human health.

Other signs of toxicity, such as reductions in body weight gain and increases in kidney weight were observed in several 14- and 90-day studies in rats with doses greater than 100 mg/kg/day.
In mice, general signs of toxicity were observed in a 90-day study at doses > 1000 mg/kg/day. NOAELs, for effects considered relevant to human health, are therefore established at 100 and 1000 mg/kg/day respectively in rats and mice (ECB, 2000).

Effect on reproduction and offspring
No information has been available for reproductive effects in humans in the EU RAR (ECB, 2000). No animal studies specifically investigating reproductive effects could be identified. However, in a repeated exposure toxicity study, female rats showed a decrease in ovary weight, following administration of SCCPs by gavage of 3000 mg/kg/day for 14 days. Other signs of toxicity, including a 20% decrease in body weight gain, were also noted at this dose level and the effect on the ovaries is likely to be secondary to this. No changes were seen in the ovary at a dose of 1000 mg/kg/day. No changes were seen in the seminal vesicles, prostate, testes, ovaries or uterus when rats and mice were treated for 13 weeks with SCCPs at doses of up to 5000 and 2000 mg/kg/day, respectively.

In a study, rats were treated with 0, 100, 500, or 2000 mg/kg on day 6 to 19 of gestation with SCCPs with a chlorination degree of 58% maternal toxicity and developmental effects were observed. Maternal toxicity was observed in the mid- and top-dose groups, while developmental effects were only observed in the top-dose group, which also showed severe maternal toxicity including death (ECB, 2000).

SCCPs are known to be transferred to the offspring via milk. However, fertility studies investigating the potential effects mediated via e.g. lactation are missing. A rat study with MCCPs, in contrast, has shown a specific inhibitory effect on the blood clotting system in rats, leading to haemorrhaging and mortality both in pups and the dams (see section 6.1.3). Based on the similar physico-chemical properties and toxicity profiles of SCCPs and MCCPs, it is possible that SCCPs may also exert toxic effects mediated via lactation by affecting the blood clotting system (ECHA, 2008).

No developmental effects were observed in a study in rabbits at doses which did not cause maternal toxicity (ECB, 2000).

Mutagenicity/Genotoxicity
There are relatively few data available on the genotoxicity of the different SCCP compounds. However, limited information in bacteria indicates that SCCPs (50-60% chlorination) are not mutagenic in these systems. A gene-mutation assay with SCCPs (56% chlorination) was negative. Two well-conducted *in vivo* studies suggest that SCCPs do not produce mutagenicity in bone marrow cells or germ cells.

Overall, the available data and a consideration of the generally unreactive nature of these substances indicate that SCCPs are not mutagenic (ECB, 2000).

Carcinogenicity
No carcinogenicity data from human populations potentially exposed to SCCPs are available.

The only studies available in animals investigated the effects of a C12-chlorinated paraffin with a 60% chlorination degree. In rodent carcinogenicity studies, the SCCPs produced toxicologically significant, dose-related increases in the incidence of several tumour types. A dose-related increase in incidence of adenomas and carcinomas of the liver and thyroid was observed in mice. There was an indication of similar effects in a poor quality study in rats. These findings reflect chronic tissue damage caused by peroxisome proliferation in the liver and a long-term hormonal stimulation of the thyroid. Moreover, male rats showed an increased incidence of kidney tubular cell adenomas, which was not seen in female rats or in mice of either sex. This effect can therefore be evaluated as a male rat-specific phenomenon. Due to species differences, it was suggested that the benign tumours observed in the kidney of male rats are not likely to be relevant for human health (ECB, 2000).

Overall, the EU RAR concluded that considering the probable underlying mechanisms involved (see also information on repeated dose toxicity and mechanisms), it is likely that these carcinogenicity observations are not relevant to human health.

Because of disagreement between the Member States about this interpretation, the issue was referred to the Commission Group of Specialised Experts in the fields of Carcinogenicity, Mutagenicity and Reprotoxicity. The Specialised Experts agreed that of the tumours observed, only those in the liver, thyroid and kidney should be considered significant. Peroxisome proliferation for the liver tumours and hormonal imbalance for the thyroid, respectively, were accepted as underlying mechanisms by the Specialised Experts. No plausible mechanism was suggested for the kidney tumours. It had been noted that α2u globulin (a male specific protein[6]) might be responsible, but studies had failed to show significant levels of the protein (ECB, 2000).

[6] The protein α2u-globulin is is synthesized in the liver of male rats, but not in female or juvenile rats. It has earlier been determined that the interaction of α2u-globulin with the xeniobotic (or its metabolites) is an essential prerequisite for the development of light hydrocarbon nephropathy (Lehman-McKeeman, 1997).

The group therefore concluded that there was "*insufficient evidence to conclude that the kidney tumours were a male rat specific event*", and consequently the significance for humans could not be ruled out. Furthermore, it was recognised that evidence regarding the mechanism underlying the development of the kidney tumours was not definitive. Given that SCCPs are not genotoxic, it is considered that there would be no risk of kidney tumour development associated with exposures lower than those required to produce chronic toxicity in the kidney. Therefore, the NOAEL established for kidney toxicity in male rats of 100 mg/kg/day is also considered the NOAEL for kidney carcinogenicity in the EU RAR (ECB, 2000).

The discussion on carcinogenicity of SCCPs was reopened at the time of the EU RAR for MCCPs (ECB, 2008), which was published in 2008, eight years after the EU RAR for SCCPs. The RAR on MCCPs (ECB, 2008) concluded, based on newer mechanistic evidence, that the underlying mechanism for kidney toxicity of SCCPs is not of relevance for human health. Therefore, SCCPs "*should be considered not to pose a carcinogenic hazard to humans*". This argumentation was used for MCCPs, resulting in no classification with respect to carcinogenicity of MCCP (compare the corresponding section under 6.1.3).

But since there were still uncertainties about the mechanism for the kidney tumours, the expert group concluded that the criteria for no classification for SCCPs were not met. Consequently, the classification of SCCPs as Carc Cat 3 has been retained.

Endocrine disruption

Endocrine disrupting effects are not addressed in the EU RAR.

The EU strategy for endocrine disruptors includes the task of compiling a candidate list of potential endocrine disruptors that must be evaluated further for endocrine disrupting effects. In order to prioritize the efforts, the substances on the list have been subdivided into a number of categories (EC, 2011).

SCCPs and MCCPs are both on the priority list in the EU of potential endocrine disruptors as shown in Table 36. As regards human health, both substances are assigned to Category 1 including substances for which there is evidence of endocrine disrupting activity in at least one species using intact animals. For the SCCPs, the effects concern decrease in ovary weight, number of postimplantation losses and decrease in viable foetuses per dam. For the MCCPs, the effects concern decreased hepatic vitamin A levels, histopathological changes in thyroid, decreased plasma T4 and increased TSH (thyroid stimulating hormone) (EC, 2002). For both substance groups, no (or insufficient) data was gathered for a classification in wildlife (CAT 3b).

TABLE 36

CHLORINATED PARAFFINS LISTED IN THE EU PRIORITY LIST OF POTENTIAL ENDOCRINE DISRUPTORS (EC, 2013)

CAS No	Chemical name (as indicated in the list)	Human health	Wildlife	Overall category
85535-84-8	Short chain chlorinated paraffins	CAT1	CAT3b	CAT1
85535-85-9	Intermediate chain chlorinated paraffins	CAT1	CAT3b	CAT1

CAT 1: At least one study providing evidence of endocrine disruption in an intact organism. Not a formal weight of evidence approach.

CAT3b: Substances with no or insufficient data gathered.

Mechanisms and interactions

A number of mechanistic studies with rats, mice and guinea-pigs have been reviewed in the EU RAR (ECB, 2000). The intention with these studies was to investigate the possible mechanisms of the toxic effects observed in animals, in order to establish their relevance to humans.

The results indicate that SCCPs produce peroxisome proliferation in rats and mice, which is presumably the cause for the observed liver effects. Peroxisome proliferation has been demonstrated by microscopy, morphometric analysis and marker enzyme activity. Peroxisome proliferation was not observed in studies in guinea pigs, which are known to be insensitive to this effect. Similarly, humans are also recognised to be insensitive to the effects of peroxisomal proliferating agents. Therefore, it can be concluded that liver damage observed in studies in rats and mice is not relevant to human health.

SCCPs have also been shown to cause effects in the thyroid in rats and mice but not in the guinea-pig. Hepatic enzyme and hormone studies indicate that these effects are caused by a stimulation of the thyroid via negative feedback mechanisms, which is explained as follows:
"*The chain of events starts with a liver effect, namely an increase in* [the liver enzyme] *UDPG-transferase. The UDPG transferase activity results in an increase in excretion of* [the thyroid hormone] *T4 and a resultant decrease in plasma T4 levels. The decrease in plasma T4 produces an increase in the release of pituitary TSH which in turn triggers a compensatory increase in the production of T4 by the thyroid. Since T4 is continually excreted and the thyroid stimulated, the increased activity in the thyroid eventually leads to hypertrophy, hyperplasia and as a consequence, a tendency to develop thyroid tumours.*

It is possible that the increase in UDPG-transferase activity is a direct consequence of peroxisome proliferation or alternatively that it is triggered by the same mechanism as that producing peroxisome proliferation. However, from the evidence available, it is not clear whether or not the two are linked, although neither peroxisome proliferation nor thyroid effects (including changes in plasma T4 and TSH) were seen in studies in guinea pigs at high doses of 1000 mg/kg/day."

Therefore, it has been suggested that rodents are particularly susceptible to changes in the thyroid due to the absence of a T4-binding globulin. This specific globulin has a very high affinity for binding T4 and is present in humans but not in rodents. Other binding proteins are present in rodents; however, their binding efficiency is considerably smaller compared to the T4-binding globulin. In the absence of the T4-binding globulin, more unbound T4 is available for metabolism, and thus excretion, from the body.

In contrast, humans are likely to be less susceptible to changes in plasma levels of T4 and to the subsequent thyroid stimulation due to T4-binding globulin. Therefore, the effects seen in the thyroid in rats and mice are considered unlikely to be relevant to human health in the EU RAR (ECB, 2000).

The evidence regarding the mechanism underlying the development of the kidney tumours could not be evaluated as definitive, even though some studies indicated the male rat-specific α_{2u} globulin might be deposited in the proximal convoluted tubules, thus responsible for the tumour development (ECB, 2000).

6.1.3 Medium-chain chlorinated paraffins

Human health data are available from the draft version of the EU RAR on human health (ECB, 2008). Overall, it was evaluated as reasonable to use 'read-across' of toxicological data from SCCPs in cases where data for the MCCPs did not exist. This general approach is justified by the fact that apart from a small difference in number of carbon atoms in the main 'backbone' of the molecules, there is little structural difference and little difference in physicochemical properties between MCCPs and SCCPs.

Toxicokinetics and metabolism
Inhalation studies are not available for MCCPs. With regard to the physico-chemical properties of MCCPs, it is assumed that inhalation absorption is unlikely to be higher than 50% (ECB, 2008).

Oral absorption as well as distribution has been studied in rodents. The studies as reviewed in the RAR (ECB, 2008) indicate that MCCPs are absorbed following oral administration (probably at least 50% of total dose) and are widely distributed in the body. The available absorption data do not allow any conclusions regarding the relationship between chlorination degree and the extent of absorption following oral administration (or any other route). *In vivo* studies investigating dermal absorption of MCCPs have not been available. An *in vitro* study using human skin showed absorption of approximately 0.7% of a C15 chlorinated paraffin after 24 hours, leading to the assumption that a dermal absorption value of 1% would be appropriate for the risk characterisation (ECB, 2008).

After absorption, MCCPs in rats could be detected in liver, kidney, ovaries, adrenal glands and adipose tissue. Several studies showed that initial tissue concentrations were highest in liver and kidney tissues, but declined within a few days (half-lifes of 2-5 days). Distribution into adipose tissue was slower, reaching the highest levels after declines in the other tissues. An elimination half-life from adipose tissue of 2 and 8 weeks was measured, the latter leading to the conclusion that MCCPs are sequestered for a prolonged period in adipose tissue and therefore have the potential to accumulate in this tissue.

In relation to metabolism, one study with MCCPs with a chlorination degree of 65% indicated conjugation with glutathione. The production of CO2 from MCCPs has also been demonstrated; furthermore, an inversely proportional relationship between metabolism to CO2 and chlorination degree could be detected.

The faeces was the major route of elimination of MCCPs and/or their metabolites, while excretion via urine and exhaled air was limited, accounting for less than 3% and 0.3% in rats, respectively.

Acute toxicity
There is no information available on acute effects of MCCPs in humans. With respect to animal studies, inhalation and dermal exposure studies are also lacking. However, based on inhalation data for SCCPs and oral animal data for MCCPs, the RAR concludes:
"*MCCPs are of low acute oral toxicity with no deaths and only limited, non-specific clinical signs of toxicity resulting from exposure of rats to very high doses (up to 15000 mg.kg^{-1}).*"

The authors note that it was not possible to clearly differentiate whether the non-specific effects were caused by exposure to SCCPs and/or MCCPs. Furthermore, it is not clear whether low concentrations of 'epoxy stabiliser' in some of the test substances might have an effect on the toxicological profile of MCCPs.

Based on the low dermal toxicity of SCCPs and low oral toxicity of MCCPs, the RAR predicts that MCCPs are of low acute dermal toxicity. Moreover, it is suggested to be unlikely that the chlorination degree is of significance for this endpoint (ECB, 2008).

Irritation and sensitization
There are no data available regarding human skin and eye irritation. In animal studies, single exposure to MCCPs has been shown to cause only slight skin irritation and slight eye irritation. The latter corresponds to findings arising from repeated exposures of the eyes with SCCPs. The observation of somewhat more pronounced irritation following repeated application to the skin is considered to be due to a defatting action of the substances.

Due to the low skin and eye irritation potential, the generally unreactive nature of the substances, and the lack of human reports, it is anticipated that MCCPs are unlikely to cause respiratory irritation. The same conclusion applies to skin and respiratory sensitisation potential, supported by guinea pig maximisation tests showing no evidence of skin sensitisation. Again, the degree of chlorination does not appear to be of significance for these endpoints.

Sub-chronic and chronic toxicity

No human data are available. In animals there are no data relating to repeated inhalation or dermal exposure. A number of oral studies in several rodent species are available which have investigated the repeated dose toxicity of MCCPs with a chlorination degree of 40% or 52%. In the absence of any information on MCCPs outside this range, it is not possible to assess whether or not the degree of chlorination would have an effect upon the resulting toxicity.

The liver, thyroid and kidney have been identified as the target organs for repeated dose toxicity of MCCPs. For the liver, increases in weight were seen in rats and dogs at exposure levels of ≥ 100 mg/kg/day. Other liver effects were enzyme induction and histopathological changes in rats and dogs (limited study) starting from 222 and 30 mg/kg/day, respectively. These changes are suggested to be related to an increase in metabolic demand as an adaptive response, possibly combined with peroxisome proliferation in the rat at higher dose levels. Therefore, those hepatic effects are considered to be of no or limited toxicological significance to human health.

Single cell necrosis was observed in male/female rats exposed to 360/420 mg/kg/day. This effect is not thought to be related to increased metabolic demand or to peroxisome proliferation, and therefore is considered to be of relevance to human health.

For the thyroid, no toxicologically significant effects on thyroid hormones and TSH were observed up to the top dose of 222/242 mg/kg/day (males/females) in a recent 90-day study in rats, which was evaluated as 'well-conducted' (ECB, 2008). However, due to differences in the toxicity mechanism between rodents and humans, the thyroid effects observed in rats should not be considered of relevance to human health at relevant levels of exposure.

No adverse renal effects were seen in male and female rats at 23 mg/kg/day in a recent and well-conducted 90-day study. Changes in the kidneys were observed at ≥ 222 mg/kg/day (increased weight, 'chronic nephritis' and tubular pigmentation) and are considered as being potentially relevant to human health. In terms of severity, an increase in kidney weight of 9-13% was observed at the top dose of 222 mg/kg/day in one study and of 18% at the top dose of 625 mg/kg/day in another study. Kidney changes were also observed in treated males from a dose of 10 mg/kg/day; however, in this dose group the changes were not significantly different from the controls.

Overall, a NOAEL of 23 mg/kg/day is established in the draft RAR for repeated dose toxicity based upon effects seen in the rat kidney. At 222 mg/kg/day, increased weight, chronic nephritis and also slight decreases in plasma triglycerides and cholesterol levels were observed. Tubular pigmentation occurred at 625 mg/kg/day (ECB, 2008).

Effect on reproduction and offspring

According to the draft RAR (ECB, 2008), no information on fertility effects in humans is available. Two available animal studies showed that administration of up to approximately 100 and 400 mg/kg/day in the diet, respectively, had no apparent effect upon fertility. Maternal death during parturition was demonstrated in one out of the three reported studies in dams that were dosed with 6250 ppm (538 mg/kg/day). The maternal death is not considered a direct consequence of parturition, but rather as a consequence of low levels of vitamin K[7] and related haemorrhaging (consult

[7] Vitamin K is necessary for the production of blood-clotting proteins in the liver.

section 6.1.3 Medium-chain chlorinated paraffins/ Mechanisms and interactions for further details on haemorrhaging effects). Moreover, dams are considered to be at higher risk due to the act of parturition.

In relation to developmental effects, no human data have been available. No adverse effects occurring during gestation were produced in rats or rabbits in two conventional teratology studies using doses of up to 5000 and 100 mg/kg/day respectively. In contrast, exposure of rats to MCCPs (52% chlorination) from 74 mg/kg/day (1000 ppm) up to approximately 400 mg/kg/day (6250 ppm) in the diet produced internal haemorrhaging and deaths in the neonatal pups. These effects were, however, not observed in a more recent teratology study with exposure to MCCPs for 11-12 weeks at maternal dose levels of 23 (300 ppm), 47 (600 ppm) and up to 100 mg/kg/day (1200 ppm). These effects would therefore appear to be a repeated dose effect to which neonates during lactation, and possibly pregnant females at the time of parturition, are particularly susceptible.

A recent investigation has shown that MCCPs at a dose level of 6250 ppm (538 mg/kg/day) induce a perturbation of the clotting system in lactating neonates of treated mothers. In adult females that had been treated for 7-8 weeks including pregnancy and lactation, decreased levels of vitamin K and of the clotting factors VII and X were found, and 5 out of 32 dams showed signs of haemorrhaging during parturition.

Some study authors proposed that the administered MCCPs dose was either transferred to the breast milk, causing disruption of the clotting system in the pups, or alternatively that the pups received less vitamin K in the breast milk as a result of treatment-related effects upon their mothers, and therefore the vitamin K-dependent clotting pathway was impaired.

The RAR summarises the no effect concentrations as follows:
"*From the studies available, an overall NOAEL of 47 mg/kg/day (600 ppm) as a maternal dose can be identified for these effects mediated via lactation. However, it should be noted that the effects (11% reduction in pup survival and related haemorrhaging) observed at the LOAEL (74 mg/kg/day; 1000 ppm) were not statistically significant. Haemorrhaging was also seen in one study at the time of parturition in 16% of dams given 538 mg/kg/day (6250 ppm) MCCPs, but not up to 100 mg/kg (1200 ppm) in other studies. The NOAEL of 100 mg/kg/day (1200 ppm) is therefore selected for the risk characterisation of haemorrhaging effects potentially occurring in pregnant women at the time of parturition."*

The RAR further states that there has been some disagreement about the interpretation of the data between the Member States. Denmark, Sweden and Norway found that the described effects concerning internal haemorrhaging and death in neonatal pups should be considered as developmental toxicity effects and not exclusively as repeated dose toxicity effects as concluded in the RAR. The reasoning behind this argument is (ECB, 2008):
"*The development during the neonatal period of rats corresponds to the development period during the last trimester of human pregnancy. It was argued that as the effect may be a consequence of increased sensitivity towards low level of vitamin K of the new-born rats this would then correspond to increased sensitivity in the human foetus during the last trimester. It was also argued that the effect would further imply classification for developmental toxicity as the criteria for classification include any effect interfering with normal development from gestation up to and including puberty*."

The interpretation of the effects as developmental toxicity was not shared in the opinion on the RAR by the EC Scientific Committee on Health and Environmental Risks (SCHER). This is justified by the fact that the effect in the rats does not occur *in utero*, where there appears to be sufficient supply of vitamin K from the dams and the same can be assumed for humans (SCHER, 2008).

Mutagenicity/Genotoxicity
A few bacterial cell studies and a few rat and mouse *in vivo* studies investigating mutagenic effects have been available. No human data could be identified.

MCCPs (40-52% chlorination) are not mutagenic to bacteria. A gene mutation assay, as well as *in vivo* genotoxicity tests in somatic and germ cells treated with SCCPs, have obtained negative results. No genotoxicity of MCCPs was observed in three *in vivo* bone marrow studies.

Overall, the available data on MCCPs and SCCPs indicate that MCCPs do not possess genotoxic activity. However, due to the lack of data, the consequences of chlorination degree for mutagenic potential of the substances remains largely investigated.

Carcinogenicity
Neither carcinogenicity data from human populations with potential exposure to MCCPs, nor investigations in animals are available. Generally, MCCPs are unreactive and not mutagenic. Given the similarities between MCCPs and SCCPs with regard to physico-chemical properties and similar results obtained in relation to different toxicological endpoints (in particular the effects seen on the liver, thyroid and kidneys on repeated exposure), it seems reasonable to presume that the carcinogenic potential of MCCPs will be similar, at least in qualitative terms, to that of SCCPs (ECB, 2008).

The carcinogenic effects of SCCPs have been described as follows in the RAR (ECB, 2008):
"*SCCPs have been investigated in animal studies and found to induce liver, thyroid and kidney tubular cell adenomas and carcinomas. On mechanistic considerations, the liver and thyroid tumours were considered to be of little or no relevance to human health. The underlying mechanism for the kidney tumours has not been fully elucidated. However, there is recent mechanistic evidence to show that α2u-binding is probably the primary mechanism for kidney tumour formation induced by SCCPs in male rats. The available evidence strongly suggests that the underlying mechanism would not be relevant to humans. Therefore, overall, SCCPs, and by analogy MCCPs, should be considered not to pose a carcinogenic hazard to humans.*"

However, due to uncertainties about the mechanism for the kidney tumours, this issue has been re-evaluated by the EC Group of Specialised Experts in the fields of Carcinogenicity, Mutagenicity and Reprotoxicity. The Specialised Experts agreed that there were still data gaps leading to uncertainty about the relevance of these tumours for humans, as well as inconsistencies and contradictions in the mechanistic studies which do not allow for sufficient understanding of the carcinogenic action of SCCPs. Therefore, the Experts concluded that the criteria for no classification for SCCPs were not met, and hence recommended that the current classification of SCCPs with Carc Cat 3 should be retained.

Nonetheless, the Specialised Experts agreed that a read-across from SCCPs to MCCPs was not justified for carcinogenicity (ECB, 2008). This is presumably related to the uncertainty about the toxic mechanism of SCCPs rather than to the uncertainty about the adequacy of the read-across approach for the substances. Consequently MCCPs could not be classified for this endpoint. Still, in terms of hazard and risk, the carcinogenic potential of MCCPs has been addressed in the RAR. Taking into account all the other existing data on MCCPs, specifically the genotoxicity and the repeated dose toxicity data, it is noted that MCCPs do not demonstrate genotoxic activity, but do produce kidney toxicity in male and female rats. Based on this evidence, it cannot be completely ruled out that this form of kidney toxicity might lead to cancer through a non-genotoxic mode of action. Therefore, for the risk characterisation on the carcinogenicity endpoint, the same NOAEL of 23 mg/kg/day as identified for repeated dose effects on the kidney was applied in the RAR (ECB, 2008).

Endocrine disruption
There is no information on endocrine disrupting effects available in the RAR. However, with respect to human health, MCCPs are categorised as CAT 1 on the candidate list in the EU of endocrine disruptors (see the corresponding section on endocrine disruption of SCCP).

Mechanisms and interactions
The mechanistic studies reviewed in the RAR have shown that MCCPs are capable of eliciting hepatic enzyme induction and proliferation of smooth endoplasmic reticulum. These effects are a consequence of increased metabolic demand arising from xenobiotic metabolism and can be considered as a physiological adaptation rather than a toxicological response.

Hepatic peroxisome proliferation is induced in rats and mice at higher dose levels as evidenced by microscopy, morphometric analysis and enzyme marker activity. Peroxisome proliferation was not observed in guinea pigs (this species has been demonstrated to be relatively insensitive to the effect). Humans are also relatively insensitive to the induction of hepatic peroxisome proliferation. Thus, the hepatic changes seen in rats and mice are considered to be of limited relevance to human health.

Exposure to MCCPs has been shown to lead to thyroid effects in rat studies. Thyroid effects have not been investigated in mice or guinea pigs. One study provides evidence that the thyroid effects are caused by stimulation of this organ, arising from a negative feedback control through hepatic metabolism.[8] The continuous stimulation of the thyroid is predicted to ultimately give rise to hypertrophy and hyperplasia in this organ. In another well-conducted 90-day study in rats, no toxicologically significant effects on thyroid hormones and thyroid-stimulating hormone (TSH)[9] levels were observed up to a dose of 222/242 mg/kg/day (males/females).

It has been demonstrated that decreases in thyroid hormone levels in humans resulting from altered hepatic clearance are typically insufficient to increase TSH levels. The decreased sensitivity of the humans to hepatic clearance appears to be influenced by several important quantitative differences between rats and humans including:

- longer half-lives in humans due to efficient binding to a high affinity-globulin that is not present in the rat,
- basal activity of the thyroid gland is markedly more active in rats than in humans, and
- constitutive TSH levels are nearly 25 times higher in rats than in humans, reflecting the increased activity of the thyroid-pituitary axis in rats.

Based upon these considerations, humans are predicted to be less susceptible than rodents to fluctuations in levels of free plasma thyroid hormone and hence any subsequent thyroid stimulation arising from a reduction in free plasma thyroid hormone levels. Overall, it is considered that the thyroid effects produced in rats would be of little relevance to human health at relevant levels of exposure.

In contrast, changes seen in the kidneys (increased weight, 'chronic nephritis' and tubular pigmentation) are considered as being potentially relevant to human health. Mechanistic studies indicated some deposition of the protein α2u globulin, in proximal convoluted tubules of male rats only at higher dose levels, which, however, was not related to the pathological effects mentioned above.

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[8] The negative feedback control as explained in the RAR: *"Initially an increase in the liver enzyme UDPG-transferase is stimulated by treatment with MCCPs resulting in increased glucuronidation and consequent excretion of T4, with a resultant reduction in plasma T4 levels. The pituitary responds to the decreased levels of T4 by releasing more TSH, which in turn leads to increased production of T4 by the thyroid. The continuous stimulation of the thyroid in response to the increased excretion of plasma T4 (seen in this 14-day study) is predicted to ultimately give rise to hypertrophy and hyperplasia in this organ"* (U.K., 2008).

[9] TSH - Thyroid-stimulating hormone is a hormone that stimulates the thyroid gland to produce the thyroid hormone thyroxine (T4), which can be converted to triiodothyronine (T3) in the liver and stimulates metabolism in the whole body (Merck, 2012).

Thus, the changes are not considered to be a male rat-specific phenomenon, leading to the recognition of a NOAEL of 23 mg/kg/day.

MCCPs are potentially hazardous to pregnant women, as well as considered to present a hazard to the offspring via the lactating mother, due to haemorrhaging effects related to low vitamin K levels in the blood plasma and in the milk.

Vitamin K controls the formation of clotting factors II (prothrombin), VII, IV and X in the liver. In adults, the vitamin is synthesised by the gut microflora and also obtained from the diet. Neonates are physiologically compromised in their vitamin K status in the early days of life, where the neonatal gut is sterile. The only source of vitamin K in the neonate is therefore from breast milk, which, however, has relatively low levels of vitamin K. Moreover, the neonatal liver is immature with respect to synthesis of the clotting factor II.

Based on a mechanistic study on internal haemorrhages which observed decreases in the clotting factor X in pups from mothers treated with chlorinated paraffins, the hypothesis of MCCP-induced catabolism of the vitamin K in adult female rats was developed and tested in two studies from 2003 and 2004.

The two studies gave partly contradicting results; the first one concluded that MCCPs are without effect on the blood clotting system in adult female rats (treated for 3 weeks up to a dose level of 1000 mg/kg/day). The haemorrhaging effects on the offspring are therefore unlikely to be mediated by reduced vitamin K levels in breast milk.

The second study observed that the foetus *in utero* apparently receives sufficient vitamin K via the placenta. After birth, however, the neonatal becomes severely deficient in vitamin K and related clotting factors due to low levels in the milk. Additionally, the neonates receive considerable levels of MCCPs through the milk, possibly further reducing their vitamin K levels. Both factors contribute to severe vitamin K deficiency and consequently to haemorrhaging (ECB, 2008).

6.1.4 Combination effects

Since placing on the market and use of SCCPs is prohibited in the EU except for a few allowed uses, combination effects of SCCPs and MCCPs are of less relevance for the future. However, SCCPs may still be present, e.g. in low concentrations in mixtures, and therefore combined exposure cannot be ruled out completely. In addition, secondary exposure to SCCPs still present in different materials such as building materials is also possible.

UNEP (2011) has published a case study on toxicological interactions of chlorinated paraffins suggesting a methodology for assessing toxicity from combined exposures. The two main methods which are considered are concentration (dose) addition and independent action. Dose addition is most appropriate if each component expresses its toxicity by the same mode of action, whereas independent action is most appropriate if each component expresses its toxicity on a given endpoint by a different mode of action. No studies involving combined exposure to both types of chlorinated paraffins are identified by the authors of the case study.

In the case of chlorinated paraffins, the similarity of the effects seen from exposure to SCCPs and MCCPs suggests a similar mode of action and, therefore, application of the dose addition approach as the most appropriate. This means that when assessing the risk related to exposures from chlorinated paraffins using the 'margin of safety' approach, then the calculation should be based on an addition of the daily dose of SCCPs divided by the NOAEL for SCCPs for the selected endpoint to the daily dose of MCCPs divided by the NOAEL for MCCPs for the selected endpoint (UNEP, 2011).

6.1.5 No effect levels

No observed adverse effect concentrations

No observed effect concentrations (NOEC) or no observed adverse effect levels (NOAEL) for SCCPs and MCCPs as given in the RARs have been summarised in Table 37. No NOEC/NOAEL based on inhalation or dermal exposures have been available. The lowest values derived from oral exposure studies are related to effects on the kidney.

TABLE 37
NO OBSERVED EFFECT CONCENTRATIONS OF SCCPS AND MCCPS

Organism	Exposure	Effect	NOEC/NOAEL	Reference
SCCP				
Rat	Oral, several studies, 14- and 90-day studies	Reductions in body weight gain, increases in kidney weight	100 mg/kg/day	ECB, 2000
Mice	Oral, 90-day study	General signs of toxicity	1000 mg/kg/day	ECB, 2000
Rat	Oral, several studies, 14- and 90-day studies	Kidney carcinogenicity	100 mg/kg/day	ECB, 2000
Rat	Oral, on days 6 to 19 of gestation	Developmental effects	500 mg/kg/day	ECB, 2000
Rat	Oral, 13 weeks	Microscopic changes in liver, kidney and thyroid	10 mg/kg/day*	ECHA, 2008
MCCP				
Rat	Oral, 90-day study	Effects in the kidney	23 mg/kg/day	ECB, 2008
Rat	Oral, 11-12 weeks	Reduction in pup survival, mediated via lactation	47 mg/kg/day	ECB, 2008
Rat	Oral, 11-12 weeks	Internal haemorrhaging effects in pregnant dams	100 mg/kg/day	ECB, 2008
Rat	Oral, several studies, 14- and 90-day studies	Kidney carcinogenicity	23 mg/kg/day	ECB, 2008

* The rat study from which this NOAEL is derived has also been included in the EU RAR (cited as Serrone *et al.*, 1987 in ECB, 2000), but the effects have originally been interpreted as adaptive, while the more recent interpretations consider them as *adverse*, leading to the derivation of this NOAEL (ECHA, 2008).

Tolerable daily intake (TDI)

A TDI of 100 µg/kg bw/day for non-neoplastic effects of SCCPs for the general population has been derived by the International Programme on Chemical Safety (IPCS, 1996) under consideration of the lowest reported no-observed-effect level of 10 mg/kg bw/day in a 13-week study in rats and an assessment factor of 100 (10 for interspecies variation; 10 for intraspecies variation).

For MCCPs, a TDI of 100 µg/kg bw/day for non-neoplastic effects has been developed, likewise under consideration of the lowest no-observed-adverse-effect level of 10 mg/kg bw/day and an assessment factor of 100 (10 for interspecies variation; 10 for intraspecies variation) (IPCS, 1996).

The Canadian EPA calculated a TDI of 6 µg/kg bw/day for MCCPs derived from a NOAEL of 0.4 mg/kg bw/day in a subchronic study conducted by Health Canada (Environment Canada, 2008).

Nielsen and Ladefoged (2013) have calculated a TDI of 100 µg/kg bw/day for the sum of chlorinated paraffins based on the same considerations as described above.

Occupational exposure limits
Neither European nor Danish occupational exposure limit values could be identified for the substances. In Germany, a long term limit value for respiratory fraction of MCCPs in air has been defined at 0.3 ml/m³ (6 mg/m³). This value may be exceeded by a factor of 8 for max. 15 min, 4 times during a shift (GESTIS Substance Database, 2014).

6.2 Human exposure

6.2.1 Direct exposure

SCCPs
Occupational exposure - Occupational exposures originating from manufacturing, formulation, and use of formulations of SCCPs are described in the EU RAR (ECB, 2000). Since production and use of SCCPs is restricted nowadays, the current exposure from these sources can be assumed to be negligible in occupational environments. In addition, occupational health and safety legislation requires that workers must be protected from exposures to chlorinated paraffins, e.g. through the use of personal protective equipment.

In the case of work involving possible exposure from e.g. removal of old mortar joint, workers must use personal protective equipment such as respiratory protection, gloves and full body protection in order to comply adequately with occupational health and safety legislation.

Consumer exposure - Consumer exposure may still arise from the use of finished products containing SCCPs. The possible exposure for consumers as estimated in the RAR is summarised in Table 38.

The only uses leading to non-negligible exposure were use of leather clothing and metal working fluids. It is emphasised that the suggested scenarios represent worst-case scenarios, as current exposures can be assumed to be (even) smaller since fewer products and formulations containing SCCPs are expected to be on the market. The estimated exposure to SCCPs in leather clothes is based on a maximum concentration of 1 % chlorinated paraffins in leather goods. This fraction is obtained in the RAR through communication with the leather industry (ECB, 2008).

MCCPs
Occupational exposure - Occupational exposures to MCCPs occur during manufacture of the substance as well as manufacture of formulations. Occupational use of MCCPs is covered by the occupational health and safety regulation and the exposure must be minimized.

The following exposure scenarios have been considered in the RAR (ECB, 2008);
- Manufacture of MCCPs;
- Manufacture of PVC formulations containing MCCPs and their use;
- Manufacture and use of paints containing MCCPs;
- Manufacture and use of sealants and adhesives containing MCCPs;
- Manufacture of rubber containing MCCPs;
- Manufacture and use of metalworking fluids containing MCCPs;
- Manufacture and use of fat liquors for leather treatment; and
- Manufacture of carbonless copy paper containing MCCPs.

TABLE 38
SUMMARY OF CONSUMER EXPOSURE TO SCCPS (ECB, 2000)

Scenario	Inhalation		Dermal		Comment on the scenario according to statements in the RAR
	Duration	Dose	Duration	Dose	
Leather slippers		negligible	Daily	<10 mg	
Leather clothing		negligible	Daily	137 mg	Consumer wears leather trousers and jacket next to the skin continuously – estimate likely to be an exaggeration
Textiles		negligible		negligible	Treated textiles are sail cloths, industrial protective clothing and tarpaulins - consumer contact with these products would be very intermittent
Metal working fluids	per event, two hours	0.3 mg	per event, two hours	200 mg	Exposure information from occupational estimate - likely to be an overestimate for consumers
Paints, sealants & adhesives		negligible		negligible	SCCPs are not used in the kinds of paints, sealants or adhesives commonly purchased by consumers – the exposure is therefore rare
Rubber products		negligible		negligible	Given the nature of the products and their paraffin content, for the purposes of risk assessment, inhalation and dermal exposure arising from the use of finished products can be considered to be negligible.

With respect to metalworking fluids (MWFs), two scenarios are considered: water-based and oil-based MWF, because they differ in the MCCP content. The exposure data presented in the RAR is based on model predictions (EASE[10]), information from industry and measured data.

Industry has provided measured exposure data for PVC compounding, extrusion, calendering, plastisol manufacture and use, and rubber manufacture. Individuals were sampled for the majority of the working shift and results are indicative of 8-hour time weighted averages (TWAs).
For all other scenarios, the EASE model has been used to predict exposures of workers to airborne MCCP. However, the very low vapour pressure of MCCPs has meant that the EASE parameters are at the limits of the model's facility to predict exposure.

Thus for the lowest exposure, the upper limit of 0-0.1 ppm by far exceeds the saturated vapour concentration[11] for MCCPs at ambient temperature, i.e. 0.0027 ppm (0.051 mg/m^3). In processes which operate at temperature above 100 °C (e.g. hot-processing of plasticised PVC formulations at

[10] Estimation and Assessment of Substance Exposure - general purpose predictive model for workplace exposure assessments, used where measured exposure data are limited or not available.
[11] The saturated vapour concentration is the theoretical maximum achievable concentration in a steady state environment which will rarely, if ever, be achieved in practice in an industrial situation (U.K., 2008).

up to temperatures of 200 °C), MCCPs might condense to a mist once vapour laden air moves away from its high temperature source. Workers will then be exposed to both mist and vapour, even though ventilation will minimise overall exposure to MCCPs. The following inhalation exposure estimates take into account both vapour and mist exposure, but do not consider possible ventilation, and are likely to be overestimates (ECB, 2008).

As can be seen from Table 39, the largest exposures are expected to occur due to the use of oil-based metal working fluids and during calendering[12] of plasticised PVC.

TABLE 39
OCCUPATIONAL INHALATION EXPOSURE DATA FOR MCCPS (ECB, 2008)

Industry		EASE (mg/m³)	Measured data (mg/m³)	Reasonable worst case (mg/m³)
Manufacture of MCCPS		negligible		0.05
PVC formulating	PVC plastisol manufacture	negligible		0.08
PVC formulating	plastisol use	negligible		0.05
PVC formulating	calendering of plasticised PVC	9 – 18	0.03 to 1.2 (0.01, 0.03)	1
PVC formulating	compounding of plasticised PVC	9 – 18	<0.003 - 0.44	0.15 (median)
PVC formulating	extrusion and moulding of plasticised PVC	9 – 18	<0.01 - 0.4	0.1
Manufacture of paints containing MCCPs		negligible		0.05
Use of paints containing MCCPs (spraying)		5	0.002 – 0.19	0.19
Manufacture of sealants containing MCCPs		negligible		0.05
Rubber manufacture			0.01 – 0.07	0.07
Manufacture of MWFs* containing MCCPs		negligible		0.05
Use of water-based MWFs* containing MCCPs			0.008 (95th percentile)	0.008
Use of oil-based MWFs* containing MCCPs			2.4 (95th percentile)	2.4
Manufacture of fat liquor in leather treatment		negligible		0.05
Use of fat liquor in leather treatment		negligible		0.05
Manufacture of carbonless copy paper		negligible		0.05

* MWF – Metal working fluid

Correspondingly, dermal exposure has been estimated for MCCPs. Measured data have been used together with use concentration information to estimate dermal exposures to MCCPs in MWFs. All other exposure estimates have been predicted using EASE.

[12] Calendering is a process in which the hot thermoplastic material is shaped into a continuous sheet by passage through a series of heated rolls (the calender).

Table 40 shows that the by far highest dermal exposure can be expected due to handling of oil-based MWF. Using the default value for bodyweight of workers (70 kg; ECHA, 2012a) and a dermal absorption of 1%, the uptake through this exposure can be calculated as 3600 µg/kg bw/d.

TABLE 40
OCCUPATIONAL DERMAL EXPOSURE DATA FOR MCCPS (ECB, 2008)

Industry		Exposure (mg/cm²/day)	Area Exposed (cm²)	Reasonable worst case (mg/day)
Manufacture of MCCPS		0.1 – 1	210	210
PVC formulating	PVC plastisol manufacture	0.1 – 1	420	420
	plastisol use	0.03 – 0.3	420	126
	calendering of plasticised PVC	0.1 – 1	420	420
	compounding of plasticised PVC	0 – 0.1	840	84
	extrusion and moulding of plasticised PVC	0 – 0.1	210	21
Manufacture of paints containing MCCPs		0 – 0.1	420	42
Use of paints containing MCCPs (spraying)		0.015 – 0.15	840	126
Manufacture of sealants containing MCCPs		0 – 0.1	420	42
Rubber manufacture		0.1 – 1	420	420
Manufacture of MWFs* containing MCCPs		0 – 0.1	420	42
Use of water-based MWFs* containing MCCPs		36,000 mg MWF	both hands	180
Use of oil-based MWFs* containing MCCPs		36,000 mg MWF	both hands	25,000
Manufacture of fat liquor in leather treatment		0 – 0.1	420	42
Use of fat liquor in leather treatment		0 – 0.1	840	84
Manufacture of carbonless copy paper		0 – 0.1	420	42

* MWF – Metal working fluid

Consumer exposure - MCCPs are not sold directly as consumer products, and the potential for consumer exposure is considered to be low or negligible. Still, consumers might be exposed indirectly because of the use of the substances in certain products (ECB, 2008):

- In fat liquors used in leather processing;
- As an additive to adhesives and sealants;
- Use in rubber and plastics;
- As a plasticiser in paints, and
- As an additive in metal working fluids.

The maximum dermal exposure has been estimated at 1 mg/day for a consumer wearing leather coat and trousers directly in contact with skin over a one-year period. The RAR notes that this estimates is likely to significantly overestimate actual exposure. This estimated exposure is calculated based on an amount of 0.0075% MCCPs present in the leather. The fraction was derived from industry information on MCCP content in fat liquors as well as fat liquor content and uptake in raw leather. The fraction is thus substantially higher than the estimate of 1 % used for the exposure calculation in relation to SCCPs.

With respect to adhesives and sealants, inhalation and dermal exposures are assumed to be negligible, considering the infrequency and short duration of use by a consumer (fitting a window frame for example), that MCCPs form a small proportion of the final product, and the low volatility. The same negligible exposure applies to rubber and plastic (PVS) goods as well as paints.

Similarly as for SCCPs, consumers are generally not exposed to MCCPs through MWFs. However, certain individuals might be exposed through home or voluntary group use (e.g. car or engine restoring). The occupational exposures to MWF were taken as a basis for the calculation, though considering shorter exposure times and intensity (e.g. no mist formation and high temperature processing). Thus, for the use of oil-based MWFs, the estimated exposure is 0.5 mg/event (ECB, 2008).

6.2.2 Indirect exposure via the environment

Data on the intake of SCCPs and MCCPs in Denmark from food and drinking water have not been identified.

Air, drinking water and food

SCCPs - In the EU RAR, EUSES predictions have been used to estimate human exposure via the environment supplemented with real data. The human intake estimate of 20 µg/kg bw/day is considered as a reasonable worst case prediction based upon real data (ECB, 2000). However, due to the reduced emissions resulting from restricted use and production of SCCPs, this estimate has to be regarded as outdated**.**

The Canadian EPA (Environment Canada, 2008) estimated population exposure to SCCPs for 6 age groups (0 – 60+ years) considering uptake via ambient air, indoor air, drinking water, food, and soil based on measured concentrations from the respective sources. The authors state that there is some uncertainty connected to some of the sources. For all age groups, food was the major source contributing 50 – 100% to the total intake. The largest total exposure was found for babies (26 µg/kg bw/day = 0.026 mg/kg bw/day). Exposure estimates decreased with increasing age, resulting in an intake of 5.1 µg/kg bw/day for seniors (60+).

MCCPs - The EUSES model has been used to estimate various concentrations of MCCPs in food, air and drinking water. The most significant local exposure was derived for the scenario of MCCP use in leather fat liquors, amounting to 32 µg/kg bw/day. The total intake from regional sources was below 0.3 µg/kg bw/day (ECB, 2008).

For detailed information on predicted concentrations in environmental media and food sources, the reader is referred to section 5.3 of this report and the RAR on MCCP.

The Canadian EPA (Environment Canada, 2008) also estimated environmental population exposure to MCCPs. There was no contribution from ambient or indoor air, which can be explained by the lower vapour pressure of MCCPs. Again, for all age groups, food was the major source contributing 71 – 100% to the total intake. The largest total exposure was found for babies (25 µg/kg bw/day) and intake estimates decreased with increasing age, resulting in an intake of 3.47 µg/kg bw/day for seniors (60+).

Indoor climate
A Swedish working group from Stockholm University quantified human exposure to chlorinated paraffins through indoor air and dust (Fridén *et al.,* 2010). Forty-four air samples were taken from 21 houses (in some houses, samples were taken from several apartments). Only six dust samples provided sufficient material for analysis.

Chlorinated paraffins were detected in 40 out of 44 air samples (91%), and SCCPs were identified as the main constituents of the measured concentrations. The mean concentration of the sum of SCCPs and MCCPs in the 44 indoor air samples was 69 ng/m³ (median 64 ng/m³, range <5-212 ng/m³). The authors state that this concentrations is considerably higher than all measured concentrations that have been conducted in ambient air. The latter range from < 60 pg/m³ in remote Arctic regions to <1-15 ng/m³ in a UK semirural area, and 6-33 ng/m³ in the city of Stockholm (Fridén *et al.*, 2010). Therefore, indoor air may represent an important exposure pathway of chlorinated paraffins to humans.

SCCPs and MCCPs have been used for some of the same applications in buildings as PCBs (have actually substituted for PCB in many applications) and it would be relevant to assess whether the SCCPs may be considered the "new PCBs" and should have more attention the coming years. For PCBs two action levels of 300 and 3,000 ng/m³, respectively, in the indoor climate have been recommended by the Danish Health and Medicines Authority (DHMA, 2014). The action levels are based on similar levels established in Germany and based on a tolerable daily intake (TDI) of 1 -3 µg PCB/kg bw/day (Jensen, 2013). WHO currently recommends a TDI of 20 ng PCB/kg bw/day for mixtures of PCBs.

As mentioned above, the mean concentration of the sum of SCCPs and MCCPs in the 44 indoor air samples was 69 ng/m³ (median 64 ng/m³, range <5-212 ng/m³). The levels, when considering the actions levels for PCBs, and the differences in TDI between SCCPs and PCB, indicate that SCCPs in the indoor environment would not be of major concern.

Assuming an inhalation volume of 20 m³/d and a bodyweight of 60 kg (default values for exposure via the environment and general population according to ECHAs guidance on information requirements and chemical safety assessment; ECHA, 2012a), the indoor concentration of 69 ng/m³ would results in a daily intake via inhalation of 23 ng/kg bw/d.

Chlorinated paraffins (sum of SCCPs and MCCPs) were detected in all six dust samples at levels between 3 and 18 µg/g in the Swedish study. Chlorinated paraffins in dust consisted mainly of MCCPs. The concentrations were considerably lower (about 10 times lower) than the concentrations measured in a German study from 2003, but the authors also emphasize quantification problems with the dust samples (Fridén *et al.* 2010). Another German study from Bavaria also reported significantly higher concentrations in 11 house dust samples that were analysed for SCCPs and MCCPs. SCCPs concentration ranged from <0.76 – 7.14 µg/g with a mean of 2.41 µg/g, while MCCP concentration ranged from 4.12 – 237.5 µg/g with a mean of 70.7 µg/g (Coelhan *et al.*, 2011).

The partitioning between dust and air is dependent on the size of the molecules and particularly on the degree of halogenation. The higher abundance of SCCPs compared to MCCPs in the investigated indoor samples was expected due to a preferential partitioning of the smaller and more volatile chlorinated paraffins (the SCCPs) to air (Fridén *et al.* 2010).

The exposure via indoor air and dust was assessed in the Swedish study for adults and toddlers, and compared to exposure via diet. The intake estimates are summarised in Table 41. For ease of comparison, the reported diet estimates are also given in the table. The figures indicate that the diet is the dominant exposure pathway, but that the contribution from indoor air and dust may be significant for certain exposure situations. Considering that dust concentrations might be underestimated in the Swedish study, the intake via dust might even exceed intake via diet for toddlers.

TABLE 41
ESTIMATED EXPOSURE TO CHLORINATED PARAFFINS (SCCPS AND MCCPS) VIA INHALATION, DUST INGESTION, AND DIET (DATA FROM FRIDÉN *ET AL.* 2010)

	Adult		Toddler	
Vector	Median exposure (µg/d)	95%ile exposure (µg/d)	Median exposure (µg/d)	95%ile exposure (µg/d)
Indoor air	1.1	3	0.51	1.4
Dust	0.03	0.98	0.75	3.6
Diet (SCCPs only)*	6	12	3.6	6.8

* Exposure estimate from a Japanese diet study, where only SCCPs were quantified. The comparison might still be justified since many studies have shown that SCCPs constitute the major part of chlorinated paraffins in biota. Since fish and meat concentrations found in this study were similar, it is assumed that the differing diet composition with respect to meat and fish consumption between Japanese and European populations has little impact on the exposure estimate.

Perinatal exposure via breast milk
In a Swedish bio-monitoring study (see also next section on Bio-monitoring data), the exposure of breast-fed babies to chlorinated paraffins (sum of SCCPs and MCCPs) was calculated based on concentrations found in Swedish breast milk.

Under the assumption that the breast-feeding baby consumes 0.7 kg milk per day and the milk fat content is 3.1 %, the daily mean and maximum intake of chlorinated paraffins would be about 2.6 and 4.1 µg/day, respectively. If the weight of the baby is 5 kg, this corresponds to a mean intake of 0.52 µg/kg bw/day or a maximum intake of 0.82 µg/kg bw/day (Darnerud *et al.*, 2012).

6.3 Bio-monitoring data

6.3.1 Blood serum and adipose tissue
No data could be identified.

6.3.2 Human milk
The Swedish Chemicals Agency has recently published a report on chlorinated paraffins in Swedish breast milk with pooled samples from 1996 - 2010 (Darnerud *et al.*, 2012). Over 200 women participated in the study of body burdens of persistent organic pollutants, and ca. 30 breast milk samples were taken every 2nd year until 2006, and every year from 2007.

The authors found a significant difference in levels between SCCPs and MCCPs with a mean ratio between the two product groups of 7.9. As can be seen from Figure 10, neither the levels of SCCPs nor MCCPs in breast milk showed any obvious trend over time (Darnerud *et al.*, 2012). The mean concentration of SCCPs was 107 ng/g fat with minimum and maximum values of 45 and 157 ng/g fat. The corresponding values for MCCPs were 14 ng/g fat (1.1 – 30 ng/g fat weight). However, it has also to be noted that there appear to be considerable uncertainties in the data, including duplicate sample concentrations differing by a factor of three (143 vs. 45 ng/g fat for SCCPs and 7 vs. 2.2 ng/g fat for MCCPs).

The levels for both MCCPs and SCCPs have been fairly constant during the period 1996 – 2010 with no increasing or decreasing trend.

An English study also reported SCCPs' and MCCPs' concentrations in human breast milk (Thomas *et al.*, 2005) from 25 samples provided by 18 women and obtained from 2001 – 2002. The median SCCP concentration was 180 ng/g fat (range of 49 to 820 ng/g fat) and the median MCCP concentration was 21 ng/g fat (range of 6.2 to 320 ng/g fat). Therefore, SCCPs were typically present in milk fat at approximately nine times the concentration of MCCPs. The mean concentrations were clearly higher in the UK study (228 ng/g fat for SCCPs and 41 ng/g fat for MCCPs) as compared to the Swedish results (Figure 10).

The quality control of analysis in this study indicates that the SCCPs' concentration might be underestimated (spiked samples were only recovered to 60%), while there was full recovery of MCCPs (106%).

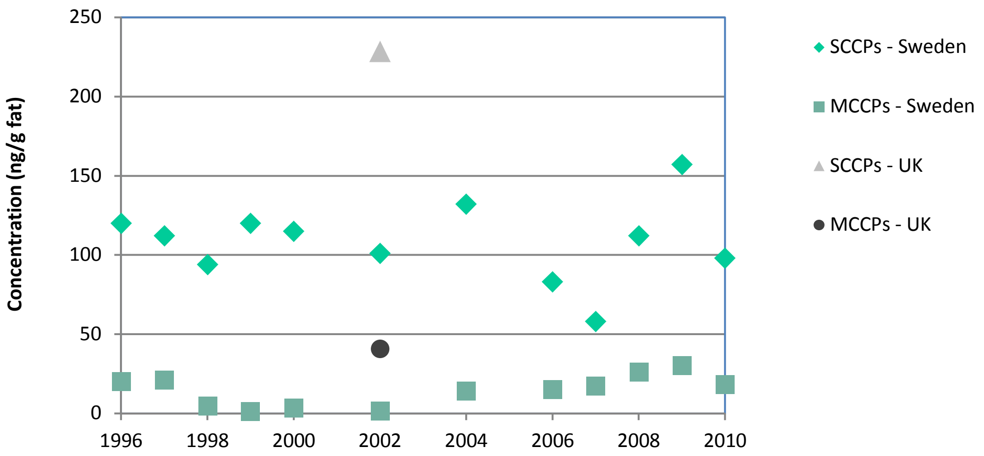

FIGURE 10
SCCP AND MCCP CONCENTRATIONS IN BREAST MILK SAMPLES FROM SWEDEN AND UK

Both studies found considerably higher concentrations of SCCPs than MCCPs in human breast milk, which is opposite to the environmental distribution of those substances (refer to section 5.3.2 on environmental monitoring data). The smaller transfer of MCCPs to humans can be assumed to be due to the differences in physico-chemical properties of the substances (most notably the vapour pressure and log K_{ow}) which cause differences in human exposure, absorption efficiency and *in vivo* processes.

6.3.3 Hair

No data were identified.

6.4 Human health impact

The information on human health risk characterisations is taken from the European Risk Assessment reports and supplemented with the more recent Canadian risk assessment on chlorinated paraffins (Environment Canada, 2008).

In the European approach, the exposure estimates from each of the relevant scenarios (covering exposures from manufacture, use and environment) are divided with the NOAELs of the identified health effects. The resulting ratio is denoted as margin of safety (MoS), meaning that a large MoS signifies a small risk and *vice versa*.

In the Canadian risk assessment, tolerable daily intakes (TDIs) have been derived from NOAELs under application of safety factors. Consequently, the risk is characterised by a comparison of TDI and exposure.

6.4.1 SCCPs

SCCPs show low acute toxicity. At the time when the EU RAR on SCCP was prepared, no health risks were identified for workers, consumers, and humans in general indirectly exposed via the environment leading to the conclusion "*ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already*". The only health risk exception was identified through the exposure in a single occupational scenario (Formulation at high temperatures; ECB, 2000), resulting in a margin of safety < 50. The conclusions are based on the NOAEL for repeated dose toxicity and carcinogenicity of 100 mg/kg/day from a study with male rats.

The reasonable worst case prediction of a SCCP intake of 20 µg/kg bw/day via the environment is also below the TDI of 100 µg/kg bw/day.

The Canadian EPA (Environment Canada, 2008) came to a different conclusion based on data and the TDI of 100 µg/kg bw/day given in the ICPS study from 1996. The exposure calculation took environmental exposure (ambient and indoor air), drinking water, food and soil ingestion into account and the exposure was estimated at 0.01 - 26 µg/kg bw/day. Therefore, the upper-bound estimate of exposure (26 µg/kg bw/day) for the age group with greatest exposure to SCCPs was assessed to be "*within the range of the TDI*", leading to the conclusion that SCCPs constitute or may constitute a danger in Canada to human life or health (Environment Canada, 2008). This interpretation may be regarded as overprotective since the TDI is still four times the highest exposure estimate, and inter- as well as intra-species variation (resulting in an assessment factor of 100) have been considered in its development.

6.4.2 MCCPs

Even though there is evidence for slight irritation of the skin as a result of repeated exposures to MCCPs, this effect is unlikely to be expressed during normal handling and use, especially under the provision of good occupational hygiene. Therefore, no further need for information was expressed on this issue (U.K. 2008).

With respect to repeated exposure toxicity and carcinogenicity, the NOAEL of 23 mg/kg, equivalent to an internal NOAEL of 11.5 mg/kg, has been applied. For all occupational exposure scenarios, sufficient safety margins could be calculated (≥ 174) apart from the scenarios for PVC calendering and use of oil-based metal working fluids (margin of safety of 88 and 3, respectively).

Conclusion (ii) ("*There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already"*) is proposed for all scenarios with a MoS ≥ 174 and PVC calendering, justified by the fact that the exposure estimate is likely to be an overestimate of chronic exposure, as workers are exposed 2-3 times per week rather than 5 days per week (U.K. 2008).

With respect to use of oil-based metal working fluids, the RAR reasons as follows: "*For oil-based MWF use, the MOS is 3. This value is considered to be too low for taking into account variability between and within species and the relatively short duration (90 days) of the study from which the NOAEL has been identified. Therefore conclusion (iii) is proposed for this scenario. It is important to note that for the oil-based MWF use scenario the MOS is heavily affected by the dermal contribution to total body burden.*" Conclusion (iii) reads "There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account", meaning that this scenario is suggested to pose a risk to human health.

Comparing the RAR occupational exposure scenarios with the long-term occupational limit value (6 mg/m^3), it does not become apparent that the air concentrations in the scenarios of PVC calendering (1 mg/m³) and use of oil-based metal working fluids (2.4 mg/m³) should pose a risk. However, it is not clear how the limit values were derived.

However, the calculated uptake resulting from dermal exposure during use of oil-based metal working fluids (3600 µg/kg bw/d) significantly exceeds the TDI of 100 µg/kg bw/d, which is in accordance with the RAR's conclusion that there might be a risk posed from this use.

For effects mediated via lactation and effects at the time of parturition, all calculations of MoS were ≥ 712, indicating no health risk. Only the MoS for use of oil-based metal working fluids were as low as 12.4 and 26 for the mentioned effects.

In summary, the RAR concluded that the MoS-values for effects on the kidney following repeated exposure for carcinogenicity, for effects via lactation and for effects at the time of parturition for oil-based metal working fluids use, were unacceptably low. For all remaining scenarios, the calculated MoS-values for all of these effects are considered to be sufficiently high (U.K. 2008).

With regard to consumer exposure, the risk assessment was performed for the two exposure scenarios resulting in actual consumer exposure (wearing of leather clothes treated with MCCPs and the use of metal working fluids). Both scenarios resulted in sufficiently high MoS-values for all relevant health effects.

The risk through indirect exposure via the environment has been calculated for regional and local exposures in the RAR leading to a MoS of 88,000 and 719, respectively, therefore not posing a risk. This finding is also in agreement with the exposure estimates (32 µg/kg bw/day and 0.3 µg/kg bw/day) being far below the available TDIs.

The Canadian EPA used a TDI of 6 µg/kg bw/day for comparison of the intake estimates via the environment (up to 25 µg/kg bw/day). Several of the highly uncertain bounding estimates of total daily intake of MCCPs from drinking water, food and soil for the general population of Canada exceed the TDI for non-neoplastic effects by up to 4-fold (for infants). Therefore, it is concluded that MCCPs constitute or may constitute a danger in Canada to human life or health (Environment Canada, 2008).

Reported concentrations of chlorinated paraffins in air and dust indicate that indoor air and dust can comprise more significant exposure routes than outdoor air (especially for toddlers) (Fridén *et al.,* 2010). However, the resulting intake estimates from air and dust are lower than the intake estimates from diet, and even the combined exposure from air, dust and food is significantly below the TDI of 100 µg/kg bw/day developed for the sum of chlorinated paraffins (Nielsen and Ladefoged, 2013). The risk for infants exposed via human breast milk and cow milk has been calculated separately based on measured concentrations. For both exposure situations, the MoS-values from all scenarios equalled or exceeded 14,800. Therefore, taking into account the knowledge of the likely mechanism, the reliability of the current breast and cow milk concentrations, the downward trend in environmental exposure and the very large safety margins obtained in spite of the highly conservative approach adopted, conclusion (ii) was proposed for these scenarios (ECB, 2008). Overall, the environmental exposure to MCCPs as assessed in the RAR does not indicate a risk to human health.

This finding is supported by the exposure estimates for the sum of SCCPs and MCCPs calculated in a Swedish breast milk study (Darnerud *et al.* 2012), the results of which are 3 orders of magnitude below the TDI.

6.5 Summary and conclusions

Human health hazard

The harmonised health hazard classifications reflect that SCCPs are suspected of causing cancer in humans, while MCCPs may cause harm to breast-fed children as indicated by their health classification.

The possible carcinogenic effects of SCCPs and MCCPs have been extensively discussed. Initiated by the risk assessment process on MCCPs, the Commission Group of Specialised Experts in the fields of Carcinogenicity, Mutagenicity and Reprotoxicity agreed that there were still data gaps leading to uncertainty about the relevance of kidney tumours for humans, as well as inconsistencies and contradictions in the mechanistic studies which do not allow for a sufficient understanding of the carcinogenic action of SCCPs. Therefore, the Experts concluded that the criteria for no classification for SCCPs were not met, and hence recommended that the current classification of SCCPs with Carc Cat 3 should be retained. They also agreed that a read-across from SCCPs to MCCPs was not justified for carcinogenicity, and consequently MCCPs were not classified for this endpoint.

Both SCCPs and MCCPs are on the candidate list in the EU of endocrine disruptors. With regard to human health, both substances are categorised as CAT 1, meaning that there is evidence of endocrine disrupting activity in at least one species using intact animals (categorization not based on a formal weight of evidence approach).

An initial assessment of available data led to the conclusion that SCCPs were not mutagenic and the same applies for MCCPs. Overall, the available data on MCCPs and SCCPs as well as the consideration of the generally unreactive nature of these substances indicate that SCCPs and MCCPs do not possess genotoxic activity. Consequences of chlorination degree are largely investigated.

Information on reproductive and developmental effects of SCCPs and MCCPs is sparse. A few animal studies showed that neither SCCPs nor MCCPs had an apparent effect upon fertility. Developmental effects of SCCPs have been observed at high doses (2,000 mg/kg), where also severe maternal toxicity was observed. No developmental effects were observed at lower doses of SCCPs (500 mg/kg and below).

MCCPs are considered to present a hazard to the offspring via the lactating mother due to haemorrhaging effects related to low vitamin K levels in the blood plasma and in the milk, contributing to their classification as Lact. (H362: May cause harm to breast-fed children). SCCPs are also known to be transferred to the offspring via milk. However, fertility studies investigating the potential effects mediated via e.g. lactation are missing. Based on the similar physico-chemical properties and toxicity profiles of SCCPs and MCCPs, it is regarded as possible that also SCCPs may exert toxic effects mediated via lactation. For MCCP, no adverse effects occurring during gestation were produced in rats or rabbits in two conventional teratology studies using doses up to 5000 and 100 mg/kg/day respectively. However, a few studies reported internal haemorrhaging, deaths in the neonatal pups, and effects mediated via lactation as a consequence of maternal, treatment-related effects. Therefore, MCCPs are considered to present a hazard to the neonatal offspring via the lactating mother. A NOAEL of 47 mg/kg/day as a maternal dose has been identified for these effects mediated via lactation.

However, Denmark, Sweden and Norway found that the described effects concerning internal haemorrhaging and death in neonatal pups should be considered as developmental toxicity effects, and not exclusively as repeated dose toxicity effects, as concluded in the RAR. However, due to mechanistic considerations, this view was not shared by the European Commission Scientific Committee on Health and Environmental Risks.

Human exposure

SCCPs

Use of SCCPs is now restricted by legislation and future direct exposure is therefore expected to be limited. Where occupational exposure still occurs, compliance with occupational health and safety legislation is expected to minimise exposure. Consumers may still be exposed through finished products containing SCCPs, e.g. in the case of leather clothes in direct contact with skin resulting in a maximum daily exposure of 137 mg/day is estimated as a conservative value, assuming a SCCP-content in leather of 1 %.

Indirect exposures via the environment have been estimated at 20 µg/kg bw/day as a worst case scenarios before introduction of restrictions in the use of SCCPs. The available data suggest that the intake of SCCPs via food contributes substantially more to the environmental exposure than intake via air and dust. Biomonitoring data suggest that the overall exposure levels have not changed significantly in recent years.

MCCPs

Occupational exposures occur during manufacture of MCCPs and during manufacture of formulations containing MCCPs. Formulations include PVC, paints, sealants and adhesives, rubber, metal-working fluid, fat liquors for leather treatment and carbonless copy paper. Occupational use of MCCPs is covered by the occupational health and safety regulation and the exposure must be minimized.

Model predictions using the EASE model indicated that reasonable worst case inhalation exposure ranged from 0.008 mg/m^3 to 2.4 mg/m^3 (use of oil-based metal working fluids) with most exposure scenarios resulting in negligible exposure.

Model predictions of reasonable worst case dermal exposure ranged from 21 mg/day to 420 mg/day for the selected scenarios, except in the case of use of oil-based metal working fluids, which resulted in a daily exposure of 25,000 mg.

As concluded in the draft EU RAR, most applications of MCCPs are not designed for consumer contact. Two scenarios are considered relevant: use of metalworking fluids, which is expected to be an infrequent event, and wearing of leather clothes, which is estimated to result in dermal exposure of 1 mg/day based on a content in leather of 0.0075 %.

Indirect exposures via the environment have been estimated for local and regional exposure at 32 µg/kg/day and 0.3 µg/kg/day respectively. In a Canadian assessment, food was the major source contributing 71 – 100% of the total intake

SCCPs and MCCPs

Based on data from a Swedish bio-monitoring study, exposure of breast-fed babies to chlorinated paraffins (sum of SCCPs and MCCPs) was calculated as a mean intake of 0.52 µg/kg bw/day or a maximum intake of 0.82 µg/kg bw/day, i.e. well below the TDI.

The median concentration of chlorinated paraffins in the indoor climate, based on findings in 40 out of 44 air samples, was 64 ng/m^3 (5-212 ng/m^3).

Biomonitoring and trends

Biomonitoring studies measuring chlorinated paraffins in human breast milk from 200 Swedish women from 1996 to 2010 and 18 women from the UK from 2001 to 2002 both demonstrated that the levels of SCCPs were considerably higher than the levels of MCCPs. In Sweden, the mean concentration of SCCPs was 107 ng/g fat and the corresponding value for MCCPs was 14 ng/g fat. In the UK, the analogous values were 180 ng/g fat and 21 ng/g fat respectively. The levels for both MCCPs and SCCPs have been fairly constant during the period 1996 – 2010, with no increasing or decreasing trend.

Human impact

SCCPs - The EU RAR identified a possible risk in a single occupational scenario. For all other scenarios covering occupational, consumer and environmental exposures, no health risks were identified. As the production and use of SCCPs is restricted nowadays, it can be assumed that the current exposures to SCCPs do not present a human health risk (ECB, 2000).

In contrast, the Canadian EPA performed a risk characterisation based on a TDI of 100 µg/kg bw/day for non-neoplastic effects of SCCPs and concluded that SCCPs constitute or may constitute a danger in Canada to human life or health (Environment Canada, 2008).

MCCPs - A single use of MCCPs, i.e. use of oil-based metal working fluids, might pose a risk to workers with respect to repeated exposure toxicity and carcinogenicity. All other occupational exposure scenarios considered in the draft EU RAR did not indicate a health risk. The same applies for effects mediated via lactation and effects at the time of parturition.

Only two exposure scenarios were evaluated as relevant for consumers and resulted in sufficiently high MoS-values for all relevant health effects, thus indicating no health risk for consumers. Likewise, the environmental exposure to MCCPs as assessed in the RAR does not indicate a risk to human health (ECB, 2008).

In contrast, the Canadian EPA performed a risk characterisation based on a TDI of 6 µg/kg bw/day for non-neoplastic effects of MCCPs and found that the worst-case exposure would exceed the TDI 4-fold. Therefore it was concluded that MCCPs constitute or may constitute a danger in Canada to human life or health (Environment Canada, 2008).

SCCPs and MCCPs – Overall, indirect exposures via the environment (food, air, water) do not cause a risk to human health. Intake via food appears to be considerably more significant than uptake via air, but combined estimates are also below the defined TDI. The same applies for infants' exposure via breast milk. However, with regard to the effects mediated via lactation, there may be uncertainty as to whether the TDI of 100 µg/kg bw/day is protective enough for infants. Even with a lower TDI the MoS (margin of safety) would however be high. Exposure estimates for the sum of SCCPs and MCCPs calculated in a Swedish breast milk study are as example 3 orders of magnitude below the TDI.

Data gaps

The underlying mechanism of male rat kidney carcinogenesis and the relevance of the observed tumours for human health still require further clarification in order to draw firm conclusions regarding the toxicity of the chlorinated paraffins and the significance of the different chain lengths and degrees of chlorination.

TDIs have not been established by EFSA for SCCPs and MCCPs and there is a need for further assessment of the exposure levels vs. TDI.

Possible endocrine disrupting effects also need further clarification.

7. Information on alternatives

Which alternatives for CPs to use often depend on the specific application and/or the desired properties in the application. This means that the alternatives available may differ, depending on whether the primary effect would be flame retardancy or a plasticising effect. In some cases, more effects are gained – and needed – from the CPs contained within, and a substitution of the CPs may require adding not just one, but more different substances to obtain a comparable performance.

For a number of applications of CPs as plasticisers/softeners, the CPs initially substituted for PCB and phthalates due to, respectively, a ban on the use of PCB and a partial substitution of phthalates because of the reduced cost of CPs compared to phthalates (ECB, 2005).

Besides the changes in the cost of raw materials, all CP alternatives will induce development costs for screening, re-formulation, tests, approval, etc. of the changed formulations and products. Some alternatives substituting for CPs may be of limited cost, while others may require substantial work to be carried out and consequently carry significant additional costs.

Another approach for avoiding the use of CPs is using different materials when possible. This has been demonstrated for e.g. sealants, where polysulphide sealants, which often contain CPs, have been substituted for some applications by (already existing) silicone and urethane sealants, since they are based on non-CP plasticisers (Zarogiannis and Nwaogu, 2010). This approach also includes the rethinking of technological possibilities such as innovative carrier or encapsulation systems, controlled release systems and immobilisation of plasticisers and/or flame retardants to ensure essential functionalities in the product.

7.1 SCCPs

Often MCCPs and LCCPs are able to replace the SCCPs (Zarogiannis and Nwaogu, 2010; US EPA, 2009), and former use of SCCPs, as suggested in information obtained by BRE *et al.* (2008), has been substituted for by the use of MCCPs in many applications. Also, brominated flame retardants (for flame retardancy) and plasticisers (as softeners) are alternatives (Zarogiannis and Nwaogu, 2010). However, some of these substances are unwanted as well, due to their potentially harmful effects to health and environment. For most major applications, less environmentally harmful alternatives to SCCPs are available, and among other suggestions include nitroalkanes, alkyl phosphate and sulfonated fatty acid esters, non-ortho-phthalates and vegetable oil-based products, which may be appropriate for specific applications (HELCOM, 2002b; UNECE, 2006; Maag, *et al.* 2010).

Since SCCPs in the EU are only allowed as flame retardants in rubber used in conveyor belts in the mining industry and as flame retardants in dam sealants, these are the main applications of interest to this survey. CEFIC has been contacted with the aim of obtaining updated information on alternatives to SCCPs for the remaining applications, but the organisation has not been in a position to provide specific information.

Zarogiannis and Nwaogu (2010) reviewed suggestions for SCCP alternatives in general rubber formulations from e.g. Peter Fisk Associates (2003), OSPAR Commission (2006) and BiPRO (2007), including e.g. inorganic flame retardants such as antimony trioxide and aluminium trihydroxide; brominated flame retardants, sulphonated fatty acid esters and organophosphorous compounds.

BRE *et al.* (2008) lists alternatives for use in conveyor belts in the mining industry as being other flame retardants recommended for use in rubber products, including MCCPs and LCCPs; an observed decline in the amount of SCCPs used for conveyer belts in the mining industry has suggested that alternatives may to some degree substitute well. A change of material to e.g. PVC containing aryl phosphate flame retardants or combined materials[13] containing alternative flame retardants (e.g. MCCPs or LCCPs covers/interlayers) may be a possible, but often more expensive, alternative to rubber that is flame-retarded with SCCPs. BRE *et al.* (2008) states that it is not clear if alternatives exist for dam sealants, and possible leaching from the sealants may present a technical barrier, thereby preventing the use of other alternatives to SCCPs. It is, however, expected that the same alternatives for dam sealants as for the conveyor belts may substitute the SCCPs. A trend showing declining use of SCCPs has been observed in dam sealants as well, suggesting that alternatives do exist. As most dam sealants seem to be applied in water-filled dams, it may be argued that a fire retardant may not be required. Should the CP have the added function as plasticiser, this could be provided with high molecule weight plasticisers which are less prone to leakage from the cured polymer. Overall, most alternatives – except MCCPs – are more costly compared to SCCPs (Zarogiannis and Nwaogu, 2010; BRE *et al.*, 2008 and references therein). A summary of possible alternatives to SCCPs in rubber is reproduced from BRE *et al.* (2008) in Table 42 below.

TABLE 42
SUMMARY OF INFORMATION ON POSSIBLE ALTERNATIVES TO SCCPS IN RUBBER (FROM BRE *ET AL.*, 2008)

Alternative	Toxicity	Ecotoxicity	Cost	Availability	Use pattern	Performance
MCCPs	Reproductive toxicant, effects on liver, kidney	R50-53; not readily biodegradable	Similar cost of substance, possible higher use rate; additional one-off costs	Commercially available	Similar to SCCPs	Technically viable alternative
LCCPs	Possible carcinogenicity and reproductive effects	Not readily biodegradable; does not meet B and T criteria	Higher cost of substance; additional one-off costs.	Commercially available	Similar to SCCPs	Technically viable alternative
Cresyl diphenyl phosphate	Toxicity to liver, kidney and blood	Does not meet P, B or T criteria	Significantly higher substance costs; additional one-off costs	Commercially available	Probable use in PVC rather than rubber	Currently used in PVC belting
Tertbutylphenyl diphenyl phosphate	Possible liver, kidney and adrenal toxicity	Does not meet P and B criteria; provisional classification R50	Significantly higher substance costs; additional one-off costs	Commercially available	Probable use in PVC rather than rubber	Currently used in PVC belting
Isopropylphenyl diphenyl phosphate	Low toxicity	Does not meet P and B criteria; acute aquatic toxicity <1 mg/l	Significantly higher substance costs; additional one-off costs	Commercially available	Probable use in PVC rather than rubber	Currently used in PVC belting

13 E.g. PVG (combination of PVC, rubber and textile) or belts with polychloroprene rubber covers.

7.2 MCCPs

MCCPs are used more widely than SCCPs, and alternatives to MCCPs are reviewed corresponding to their major use identified, i.e. in PVC, rubber, metal working fluids, sealants/adhesives and paints/coatings.

For a number of applications, LCCPs may substitute well for MCCPs, and – as for SCCPs – phthalates and other plasticisers may substitute for MCCPs as plasticisers, and flame retardants may substitute MCCPs to ensure flame retardancy. In Zarogiannis and Nwaogu (2010), which focuses primarily on SCCPs, potential alternatives to SCCPs are reviewed for rubber, sealants and adhesives as well as paints and coatings, and besides MCCPs, many of the mentioned possible SCCP alternatives are expected to be possible alternatives to MCCPs, too, and are therefore included in the review below. Further, in US EPA (2009), LCCPs are suggested as SCCP alternatives for leather, paints and coatings, sealants and rubber applications, and it is technically feasible to suggest LCCPs as substitutes for MCCPs as well.

A major producer of MCCPs in Europe states that the general conclusions given in Zarogiannis (2002) (concerning MCCPs in PVC, metal working/cutting fluids and leather fat liquors) are still valid since, to the best of their knowledge, there has been no development of new alternatives to MCCPs since 2002. However, the REACH regulation now requires the use of the primary plasticiser DEHP to be authorised, thereby in reality limiting the use of MCCPs as secondary plasticisers. MCCPs may be used with the phthalates DINP or DIDP instead, but due to decreased compatibility compared to DEHP, the use of MCCPs is reduced, according to this MCCP producer.

7.2.1 PVC

For PVC products, LCCPs and plasticiser alternatives to MCCPs are commercially available; however, not all are suitable for all PVC uses, and no single substance identified can substitute MCCPs across all applications. The phthalates DINP and DIDP have long been used as plasticisers in PVC and exhibit technical advantages compared to MCCPs, but they lack the combined plasticising and flame retarding effects of MCCPs (ENTEC, 2008; Zarogiannis, 2002; Zarogiannis and Nwaogu, 2010). Also, a number of non-ortho-phthalate plasticisers exist which can substitute for the plasticising effect of MCCPs but with higher unit prices. Examples are DEHT (di (2-ethyl-hexyl) terephthalate), DINCH (Di-isononyl-cyclohexane-1,2dicarboxylate) and COMHGA (mixture of 12-(acetoxy)-stearic acid, 2,3-bis(acetoxy)propyl ester and 0ctadecanoic acid, 2,3-(bis(acetoxy)propyl ester), with DEHT having the lowest price (Maag *et al.*, 2010).The flame retardancy of MCCPs is absent and must be provided by other means. Specifically for flame retardancy purposes, the commercially available flame retardants trialkyl phosphates, aryl phosphates and inorganic compounds such as aluminium hydroxide and aluminium polyphosphate may substitute for MCCPs as well. Also, phosphate ester compounds may provide a high level of fire resistance, though high concentrations of this substance may cause significant smoking (ENTEC, 2008; Zarogiannis, 2002).

The economic impact has been estimated at a cost increase of 20-160 % when using LCCPs, depending on application, formulation and requirements; while the phthalates DINP and DIDP may cause an increase of approx. 40-60 % as compared to MCCP costs. Phosphate esters may result in up to four times the MCCP cost, while no information on the traditional flame retardants mentioned are given. Furthermore, the costs for development and approval of new products would be added (ENTEC, 2008; Zarogiannis, 2002).

Material alternatives
The plasticised PVC with MCCPs may be replaced by other polymers/flame retardant systems.

As an example, for cables, different halogen-free flame retardants (HFFR) or low-smoke free-of-halogen (LSFOH) polymer compounds can be used in many ways to produce cables without PVC (PINFA, 2013).

Selected polymers and corresponding flame retardants, their working function and main cable applications, are shown in the table below.

TABLE 43
SELECTED NON-HALOGEN FLAME RETARDANTS USED IN HFFR CABLE COMPOUNDS AND MOST IMPORTANT END APPLICATIONS (PINFA, 2013)

Flame retardant	Working Function	Polymers/compounds	Main Applications
Aluminium trihydroxide (ATH) Magnesium dihydroxide (MDH) Aluminium oxide-hydroxide (AOH, boehmite) Zinc-borates Zinc-Hydroxystannates	In case of a fire, these mineral flame retardants decompose -absorbing energy. -releasing water (thus reducing fire intensity and diluting fire gases). -creating an oxide fire barrier against heat from the flame and to prevent burnable polymer decomposition products from reaching the flame.	Polyolefins Low-density polyethyl ene (LDPE) Polyethylene vinylacetate copolymer (EVA) Polyethylen-co-butene Polyethylen-co-octene Elastomers Natural Rubber (NR) Poly-Ethylene-Diene-Rubbers (EPDM) Poly-Styrene-Butadiene-Rubbers (SBR) Silicone rubbers (SiR) Thermoplastic Elastomers (TPE)	Electrical cables • Low voltage • Medium voltage • PV cables • Emergency lighting Control cables • Fire alarm cables Information cables • LAN cables • Telephone cables
Phosphorus flame retardants Phosphate esters (eg. Tricresyl phosphate TCP) Intumescent products based on: ammonium polyphosphates (APP), Polyphosphonates, metal phosphinates, aryl phosphates, Melamine Derivatives Red phosphorus	Flame inhibition and charring properties of phosphorusbased materials reduce the flammability of polymers. A char on the surface prevents heat transfer and protects the polymer below.	Used in fire-resistant coatings for cables Polyolefins Polypropylene (PP) Elastomers Thermoplastic Elastomers (TPE), Thermoplastic Poly Urethanes Thermoplastic Polyesters	Electrical cables • PV cables Control cables • Lift cables • Fire alarm cables

7.2.2 Metal working/cutting fluids
Metal working/cutting fluids have been determined to be the most difficult area for substitution of MCCPs because of their exceptional performance in very diverse operations as well as the price sensitivity in the field, and in particularly demanding tasks, MCCPs were still used around 2000 (Zarogiannis, 2002).

The international supplier of metal cutting/working fluids, Houghton, states that not many metal working/cutting fluids containing MCCPs are sold in Denmark and Europe, and Houghton does not explicitly promote MCCP-containing fluids. Houghton mentions sulphur compounds as acceptable alternatives to MCCPs for many operations; however, for the most demanding operations, the MCCP-containing metal working/cutting fluids are the only products performing sufficiently well.

Over time, Houghton has been involved in the development of alternatives to MCCP-containing metal working/cutting fluids. This experience includes water-based products demonstrating good performance, but requiring a change of operations from a one-step treatment to a treatment of 3-4 steps, which has not proven acceptable for a commercialisation of the product. Another supplier, Rhenus Lub, agrees with the statement that some special metal-forming applications still require the MCCP-containing metal cutting/working fluids.

A thorough mapping of non-chlorinated metal forming lubricant technologies as alternatives to CPs by contact with 50 producers of lubricants and lubricant additives has been carried out by Skak *et al.* (2005). Sixteen companies returned product information on a total of 53 available potential alternatives to chlorinated lubricants, and this data was assessed, resulting in the selection of products anticipated to fulfil a set of requirements. Nineteen lubricants free of CPs were thereafter received and subjected to technical testing at the Technical University of Denmark, where four products passed and were further tested full-scale at Danfoss A/S. None of the four alternative lubricants demonstrated a performance considered sufficient. One alternative lubricant from an internal project at Danfoss A/S is claimed technically to perform sufficiently compared to chlorinated lubricants, but due to substantial costs, it is not commercially available (Skak *et al.*, 2005). Skak *et al.* (2005) reported that chlorinated lubricants for cutting operations such as milling, screw-cutting and drilling had been completely replaced in 2005. However, for non-cutting operations, particularly demanding processes such as forming in stainless steel and titanium, chlorinated lubricants were still widely used. This usage was due to a lack of technically satisfying alternatives. At the same time, the need for lubricants to be used under very demanding production conditions is increasing due to demands for material and energy saving, increased productivity and improved quality.

Contact with suppliers of metal working/cutting fluids and additives for these products demonstrate that they offer a number of alternatives to MCCP-containing products. This includes the product example Perfad 8100 from Croda Lubricants, which claims to be a high-performance lubricant ester alternative to chlorinated paraffins, as well as chlorine-free products from Rhenus Lub, Houghton and Dover Chemical Corporation, the last of which has marketed new alternatives to MCCP-containing fluids for the last 20 years (see examples in Table 44).

TABLE 44
EXAMPLES OF METAL WORKING/CUTTING FLUIDS MARKETED AS ALTERNATIVES TO MCCP-CONTAINING (DOVER CHEMICAL CORPORATION)

Phos-Additives	Vis @ 100°F, SUS	Vis @ 40°C, cS	Vis @ 210°F, SUS	Vis @ 100°C, cS	% Sulfur	% Active	Acid #	% Phos	Comments
Doverphos 253	-	-	-	-	-	-	20	5.3	Excellent Antiwear and Antioxidant
Doverlube PE-80	-	-	-	-	-	-	320	10.8	Excellent for all operations
EM 706	1550	300	155	30	-	-	155	5.5	PE for all MW fluids
Mayphos 45	100,000	21,500	1900	400	-	-	200	5.5	Excellent for metal forming

Chlorine Alternatives	Vis @ 100°F, SUS	Vis @ 40°C, cS	Vis @ 210°F, SUS	Vis @ 100°C, cS	% Sulfur	% Active	Acid #	% Phos	Comments
Doverlube NCEP	300	65	-	-	0	N/A	10	0	S&P free Vegetable oil based EP
Mayco Base CF-95	350	75	-	-	4.5	1.5	4	0	Sulfurized sulphonate
Mayco Base CF-74	550	115	95	20	2.5	0	2	0	Sulfurized sulphonate
Doverlube NCL-2	9300	2000	-	-	0	0	125	3	Phosphorus Package
Klor Free 100	13,400	2900	1150	240	0	0	5	0	Polymeric Ester
Mayfree 133	44,000	9500	750	160	0	0	155	4	Phosamide

According to marketing material, Dover Chemical Corporation (2012) offers alternatives to CPs that may impart to extreme pressure lubricants a greener image, as the alternative CPs are stated to be readily biodegradable, offer ease of disposal, are free of stringent regulation, contain no chloride, and many additives are chlorine-free. The alternatives offered are more specific to the applications and have certain requirements regarding the formulations in which they are used; however, overall they correspond well to the alternatives listed in the literature. The CP alternatives from Dover include chlorinated fatty esters and acids, sulfurized hydrocarbons, phosphate acid esters, a phosphorous-containing blend, hydrogen phosphites (phosphonates) and a nitrogen-containing compound.

According to Zarogiannis (2002), sulphur and phosphorous compounds as well as sulphurised esters may substitute for MCCPs in a number of metal working/cutting fluids, though the performances were generally debated and not fully accepted for specifically challenging applications. In ENTEC (2008), alternatives for the use of MCCPs in metalworking fluids include e.g. polysulphides and tributyl phosphate, which may be technically suitable for some applications, although challenging applications for substitution have been identified as e.g. deep drawing, punching, extrusion, forming and drilling. Some of the suggested alternatives may pose a risk to human health (Skak *et al.* 2005).

7.2.3 Rubbers

For rubber applications, MCCPs are widely used; obvious alternatives are LCCPs, which are technically suitable in a number of applications, though they may prove too brittle for e.g. conveyor belts or demonstrate insufficient flame retardancy in bellows for busses and trains. The associated increase in raw material costs has been estimated at 20% (ENTEC, 2008). In BRE *et al.* (2008), certain LCCPs are suggested alternatives for some applications of SCCPs.

Cited in Zarogiannis and Nwaogu (2010), Dick (2001) suggests that chlorine or bromine halogen compounds may perform well as flame retardants for elastomers, while phosphate esters may act as plasticisers to replace more flammable plasticisers. Also, it is reasonable to anticipate that the summary from BRE *et al.* (2008) reproduced in Image 1 above lists alternatives that may substitute MCCPs as well as SCCPs.

7.2.4 Leather fat liquors

Already in 2002, it was stated that MCCPs have been useful additives for leather fat liquors because of their availability and low cost. They are, however, not considered essential to performance and have been effectively phased out in the UK and the EU, and their remaining use is believed to be minor and limited to specialised applications (Zarogiannis, 2002). As for other applications, alternatives to MCCPs in leather fat liquors include LCCPs and phosphorous compounds, but also sulphurised vegetable and animal oils are suggested as substitutes, since they are, in general, technically suitable (ENTEC, 2008; Zarogiannis, 2002). The raw material costs have been estimated to increase by around 20 % when substituting MCCPs with LCCPs, corresponding to approximately 2% for the fat liquor product (ENTEC, 2008).

7.2.5 Paints

According to Lassen *et al.* (2010), the European Council of Paint, Printing Ink and Artists (CEPE (2010)) states that, to their knowledge, no simple substitutions for the use of MCCPs in typically MCCP-containing coatings (industrial coatings such as marine coatings and protective (anti-corrosion) coatings) are available. The literature on MCCP alternatives in paints and coatings is very limited, while some literature exists on SCCP alternatives for these applications. Most often, this literature does not mention longer-chain CPs as possible alternatives, leaving the question open as to whether the suggested SCCP alternatives are actually relevant substitutes for MCCPs as well. This should be considered carefully while going through the overview below. The Danish industry association for paint and adhesive industries (DFL) was approached in this study, but had no specific knowledge of the use of MCCPs or alternatives.

In Zarogiannis and Nwaogu (2010), a number of possible alternative flame retardants to SCCPs for paints and coatings are mentioned with reference to Peter Fisk Associates (2003), including inorganic flame retardants such as ammonium polyphosphate, brominated flame retardants, organophosphorous compounds, halogenated compounds and nitrogen-based compounds (such as melamine derivatives). Many of them are common flame retardants, and many of them are used for intumescent paints or coatings. Further, BiPRO (2007) and ECHA (2008) are referenced for suggesting LCCPs, phosphate- and boron-containing compounds as potential alternative SCCP flame retardants.

Interviews performed by Zarogiannis and Nwaogu (2010) on alternatives to SCCPs in intumescent paints suggested organic polyalcohols, amines, acids and ester derivatives, inorganic salts based on phosphorous, boron, silicon and sulphur derivatives as possibilities. Since none responded that MCCPs may be possible alternatives, it is not clear whether the respondents find the longer-chain CPs viable substitutes to SCCPs, which, in turn, may leave it questionable if the suggested non-CP flame retardants are considered possible substitutes for MCCPs.

To achieve the plasticising effect, BiPRO (2007) and ECHA (2008) are referenced in Zarogiannis and Nwaogu (2010) as having suggested phthalate esters, polyacrylic esters and diisobutyrates as alternatives to SCCPs. DEHT, DINCH and COMGHA are deemed to be other possibilities, as mentioned above, for MCCPs. As CPs are low cost co-plasticisers rarely used alone, they are not deemed essential for the plasticising performance in the product (this will be determined by the main plasticiser(s).

7.2.6 Sealants/adhesives

In Zarogiannis (2002), focusing on MCCP alternatives, sealants and adhesives have been identified as products containing MCCPs; however, no possible alternatives have been suggested. Very little literature exists on the availability of potential alternatives to MCCPs in sealants and adhesives, while there is some literature describing possible SCCP alternatives for sealant and adhesive applications. Both BiPRO (2007) and ECHA (2008) are referenced in Zarogiannis and Nwaogu (2010) as mentioning MCCPs and LCCPs as flame retardant alternatives to SCCPs, which may imply that some alternatives suggested for SCCPs may also substitute for MCCPs in sealants and adhesives. In general, a trend of substituting polysulphide sealants, which often contain CPs, with silicone and urethane sealants (that use non-CP plasticisers instead) has been observed (Zarogiannis and Nwaogu, 2010).

HSE (2008) suggests terphenyls as possible MCCP alternatives in polysulphide sealants despite poorer performance and a price five times that of MCCPs, while diisoundecyl phthalate, polymeric plasticisers, certain phosphate plasticisers and BBP (despite inferior performance) are suggested CP alternatives by Mittal & Pizzi (2009), although they are prone to bleeding from the sealant (cited in Zarogiannis and Nwaogu, 2010). Other SCCP, and possibly also MCCP alternatives referenced in Zarogiannis and Nwaogu (2010) include DINA (di-2-ethylhexyl adipate) and DEHP as plasticisers in polysulphides; DGD (dipropylene glycol dibenzoate) in polyurethane formulations (McBride, 2010) and BBP, DGD, DEDG (diethylene glycol dibenzoate),DGD, propylene glycol alkyl phenyl ether and mixtures of these as plasticisers in acrylic polymer sealants (Mittal & Pizzi, 2009). According to Maag *et al.* (2010) DGD, ASE and DEHT are among the non-phthalate plasticisers applied in sealants and adhesives.

7.2.7 Summary

The information on alternatives to MCCPs is summarised in the following table.

TABLE 45
SUMMARY OF ALTERNATIVES TO MCCPS

CAS No	Substance group/name	Application area	Hazard Class and Category Code(s) and Hazard Statement Codes	Remark
85535-86-0	LCCPs	PVC Rubber Leather fat liquors Paint Sealants/adhesives	Not Classified	
Phthalates				
a) 28553-12-0 b) 26761-40-0 c) 85507-79-5 d) 85-68-7 e) 117-81-7	a) Diisononyl phthalate (DINP) b) Diisodecyl phthalate (DIDP) c) Diisoundecyl phthalate d) Butyl benzyl phthalate (BBP) e) Di-2-ethylhexyl phthalate (DEHP)	PVC (a + b) Paint (a+b) Sealants (polysulphide sealants) (c-e)	a) Not Classified b) Not Classified c) Not Classified d) Repr. 1B (H360Df), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410) e) Repr. 1B (H360FD)	Plasticising effect, no flame retardancy For paint and sealants: Suggested as SCCP alternatives, and the effect as MCCP alternatives is questionable
Phosphorous compounds				
	Phosphourous compounds	Leather fat liquors		
	Phosphourous compounds; in parcticular mono-, di-, and triphosphate esters and phosphonates	Metal working/cutting fluids		In general, performance is debated and not fully accepted for specifically challenging applications
	Organophosphorous and phosphate compounds	Paints		Flame retardancy; no plasticising effect Suggested as SCCP alternatives, and the effect as MCCP alternatives is questionable
	Phosphate plasticisers	Sealants		Plasticising effect, no flame retardancy
	Phosphate esters	PVC Rubber		Flame retardancy; no plasticising effect; may cause smoking (in PVC)
	Trialkyl and aryl phosphates	PVC		Flame retardancy; no plasticising effect
68333-79-9	Ammonium polyphosphate	Paints	Not Classified	Flame retardancy; no plasticising effect

CAS No	Substance group/name	Application area	Hazard Class and Category Code(s) and Hazard Statement Codes	Remark
126-73-8	Tributyl phosphate	Metal working/cutting fluids	Acute Tox. 4 (H302), Skin Irrit. 2 (H315), Carc. 2 (H351)	
Sulphur compounds				
	Sulphur-based compounds; including sulphurised esters	Metal working/cutting fluids		Performance is debated and not fully accepted for specifically challenging applications
	Sulphur-based compounds	Paints		Flame retardancy; no plasticising effect Suggested as SCCP alternatives, and the effect as MCCP alternatives is questionable
	Sulphurised vegetable and animal oils	Leather fat liquors		
a) 68515-88-8 b) 31565-23-8	Polysulphides a) Sulphurised 2,4,4-trimethyl pentene b) Di-(tert-dodecyl) pentasulfide	Metal working/cutting fluids	a) Not Classified b) Not Classified	a) Limited information on health effects available; not irritating and non-sensitising b) Based on EASE model of workplace inhalation and dermal exposures, the Danish EPA concluded that repeated inhalation of sulphurised 2,4,4-trimethyl pentene posed a risk to human health during metal forming operations.
Other compounds				
	Chlorine or bromine halogen compounds	Rubber Paints		Flame retardancy; no plasticising effect
	Boron- and silicon-based compounds; polyalcohols, amines, acids and ester derivates; polyacrylic esters; diisobutyrate	Paints		Flame retardancy; no plasticising effect Suggested as SCCP alternatives, and the effect as MCCP alternatives is questionable
27138-31-4	DGD (dipropylene glycol dibenzoate)	PVC Sealants		Plasticising effect, no flame retardancy
120-55-8	DEGD (diethylene glycol dibenzoate)	PVC Sealants		Plasticising effect, no flame retardancy

CAS No	Substance group/name	Application area	Hazard Class and Category Code(s) and Hazard Statement Codes	Remark
6422-86-2	DEHT (di (2-ethyl-hexyl) terephthalate)	General plasticiser in PVC, sealants, etc.		Plasticising effect, no flame retardancy
70775–94–10	ASE (sulfonic acids, C10 – C18-alkane, phenylesters)	PVC Sealants		Plasticising effect, no flame retardancy
736150-63-3	COMGHA (SOFT-N-SAFE™)	PVC	Not Classified	Plasticising effect, no flame retardancy
a) 21645-51-2 b) 13776-88-0	Inorganic compounds: a) Aluminium hydroxide b) Aluminium polyphosphate	PVC	a) Not Classified b) Not Classified	Flame retardancy; no plasticising effect
para 92-94-4 *meta* 92-06-8 *ortho* 84-15-1 unspec. 26140-60-3	Terphenyls	Sealants	Not Classified	Plasticising effect, no flame retardancy Suggested as SCCP alternatives, and the effect as MCCP alternatives are less documented
103-23-1	DINA (di-2-ethylhexyl adipate)	Sealants	Not Classified	
	Polymeric plasticisers	Sealants		

7.3 Historical and future trends

SCCPs have been limited to very few applications because of regulation, and often the SCCPs have been replaced by MCCPs and LCCPs. Brominated flame retardants and phthalate plasticisers as well as less environmentally harmful SCCP alternatives, including nitroalkanes, alkyl phosphates, sulphonated fatty acid esters and vegetable oil-based products, are considered as possibilities but they may not suit all applications.

Some MCCP alternatives have been identified and a few new ones developed over time, but they have not proven able to replace the MCCP properties for a number of particularly demanding processes and applications. According to suppliers, development is on-going; however, not many new alternatives have emerged, possibly due to the lack of regulation for products containing MCCPs. This trend is supported by data from the Danish Product Registry.

7.4 Summary and conclusions

Overall, the few remaining applications allowing the use of SCCPs, i.e. as flame retardants in rubber used in conveyor belts in the mining industry and as flame retardants in dam sealants, constitute a small fraction of the number of applications traditionally having used SCCPs. An observed decrease in SCCP consumption for conveyor belts as well as dam sealants indicates that applicable alternatives do exist; suggested alternatives include other flame retardants recommended for use in rubber products or the complete substitution of belt material to e.g. PVC.

Alternatives to MCCPs include many different compounds as given in the overview table above, since no single compound is able to simultaneously provide the flame retardancy and/or plasticising effect needed for all applications. Often, LCCPs are suggested as possible alternatives, while alternative plasticiser compounds may be substituted to preserve the plasticising effect and traditional flame retardants may substitute to preserve the flame retarding effect of MCCPs. Other suggested MCCP alternatives are typically phosphorous compounds or sulphur-based compounds.

The requirements for performance of MCCPs in metal working/cutting fluids is a challenge, in particular for very demanding operations, and alternatives for these have conducted proved insufficient according to the few tests. For less demanding standard operations, alternatives to CPs have been commercialised and include sulphur-based compounds and phosphate esters and phosphonates.

A key factor in the substitution of both CPs is that they are low price chemicals for the purposes in question. For some applications, the technical performance of the alternatives is not sufficient; however, for a number of applications where performance of the alternative is sufficient, the CP-containing products are still in use because of a significant difference in cost. Substituting for additively used chemicals (not chemically reacted in the material) with plasticiser function always require investments in finding the right re-formulation of the polymer mixture. The extra quality of CPs, in terms of having flame retarding characteristics, introduces an extra factor in the re-formulation work, because other substances with flame retarding effects may need to be included in the material composition.

Main data gaps

A number of challenges regarding the identification of alternatives to SCCPs and MCCPs in the relevant applications above should be considered:

- Findings are mainly available from reports, reviews and studies as well as marketing material based on SCCPs, as regulation is in force for these.
- Only limited information is available, and therefore, much information for the specific applications is obtained from just one or very few sources, which may leave some uncertainty about the conclusions.
- Marketing material and information obtained directly from approaching companies may be subjective and biased.
- Much of the obtained information is based on anticipated alternatives, while quite a few technical tests and corresponding assessments of performance as well as environmental and toxicological aspects have been considered thoroughly for this study.

8. Overall findings and conclusions

The results of the survey are summarised in the "Conclusion and summary" chapter, while this chapter summarises the main findings and issues identified and main data gaps.

8.1 Main findings

SCCPs

Production, placing on the market and use of SCCPs is in the EU prohibited by the POP Regulation. The main issue as concerns the Danish situation is the presence of SCCPs in waste. Rubber articles, paint, sealants and adhesives with an intentional content of SCCPs are considered hazardous waste and should be disposed of accordingly. Analyses of SCCPs in building materials such as sealants and window frames are still very uncommon, even though SCCPs seem to have been used for some of the same types of applications as PCB. The SCCPs have been used until the beginning of the 2000s and consequently, the major part applied would still be accumulated in the building mass. In Norway, a collection scheme for double-glazed window frames with SCCPs and MCCPs has been established as part of the collection scheme for PCB-containing windows and the CPs are covered by requirements for surveys of hazardous substances before renovation and demolition of buildings (above a certain size). In Denmark, requirements of surveys of PCBs in buildings before renovation and demolition (above a certain size) have recently been introduced.

Considering differences in tolerable daily intake (TDI) levels between SCCPs and PCBs and the levels of SCCPs measured in the indoor environment, exposure to SCCPs via the indoor air should not to be of major concern.

SCCPs have been shown to meet the REACH Annex XIII criteria for both a PBT and a vPvB substance. SCCPs are listed in Annex 1 to the UNECE POP Protocol and have been nominated by the EU for listing in the Annexes to the Stockholm Convention. The significance of the risk to health, long range transport and exposure in remote areas is, however, still under review by the POPs Review Committee.

MCCPs

MCCPs are not addressed explicitly by any EU legislation addressing products, emissions and wastes, but are still addressed by various instruments due to their harmonised classification. Work with MCCPs is covered by European and Danish occupational health and safety legislation.

MCCPs are listed in the Community Rolling Action Plan (CORAP) by the U.K. and the substance evaluation under REACH is ongoing. The PBT and vPvB status of MCCPs under REACH is still under discussion and further data are being collected as part of the REACH substance evaluation. Both SCCPs and MCCPs are multi-constituent mixtures with variable and often unknown composition, with relatively low water solubilities and high log Kow values.

It is considered unlikely that LCCPs and MCCPs are degraded in the environment to shorter-chained chlorinated paraffins, and consequently the formation of SCCPs in the environment does not appear to be an issue.

The principal uses of MCCPs are as plasticisers/flame retardants in PVC (54% of total in 2006), in paints/coatings, adhesives and sealants (18%) and rubber and other polymers (11%), as lubricant in metal working/cutting fluids (16%) and in leather fat liqueurs (1%). The total EU consumption remained stable from 1994 to 2006, where a decline in the consumption for PVC was counterbalanced by an increase in the consumption for metal working/cutting fluids, paints/coatings, adhesives and sealants and additives for rubbers and other polymers.

Imported articles are estimated to account for the majority of MCCPs in end-products used in society.

MCCPs are still used in building materials (paints/coatings, adhesives and sealants) and a significant quantity is accumulated in buildings. In Norway, the MCCPs in buildings are addressed together with the SCCPs, and it is obligatory to survey MCCPs in building materials before renovation or demolition, and to dispose of the MCCP-containing materials as hazardous waste.

In Denmark, no limit values are established in the statutory order on waste for waste containing substances classified as toxic to the environment, but the property "ecotoxic" is among the properties which may render waste hazardous. It is the responsibility of the municipalities to define whether waste containing MCCPs should be managed as hazardous waste.

The majority of the MCCPs in waste are disposed of for incineration and to landfills. According to Danish waste legislation, PVC should be separately collected. PVC which is not recycled (including flexible PVC with a possible content of MCCPs) should be landfilled in order to reduce the amount of PVC disposed of for incineration.

SCCPs and MCCPs are degraded by the incineration process and are not considered precursors for dioxins and furans but may, as any other chlorine containing substances/materials (e.g. PVC), serve as donors for "*de novo*" formation of dioxins and furans and other chlorinated POPs.

The consumption of MCCPs for different applications has been fairly stable for many years and efforts regarding the substitution of MCCPs have been limited. A key factor in the substitution of both CPs is that they are low price chemicals for the purposes in question. For some applications, the technical performance of the alternatives is not sufficient; however, for a number of applications where performance of the alternative is sufficient, the CP-containing products are still in use because of a significant difference in cost.

8.2 Data gaps

The main data gaps identified in the survey are summarised below:

Uses - Data on the remaining (exempt) uses of SCCPs in the EU are missing. It is not clear if the exemptions are still relevant.

Updated data on the consumption of MCCPs by application area at the EU level are not available in the public domain. The data may be available for the authorities from the joint REACH registration of the main MCCPs.

Data on the use of MCCPs for the production of articles of rubber and PVC in Denmark are not available.

Waste - Data on the presence of SCCPs and MCCPs in building materials in Denmark are limited. Data on the differences in the specific applications of SCCPs and MCCPs in building materials are scarce but it would an advantage to have such data for efficient identification of SCCP-containing and MCCP-containing materials. It is the responsibility of the municipalities to define whether waste containing MCPPs should be managed as hazardous waste, but no overview of how the municipalities define the MCCP-containing waste is available.

Data on SCCPs in outlets from municipal sewage treatment plants and outlets from areas with separate storm-water sewers are limited and would be relevant as the SCCPs are priority substances under the Water Framework Directive.

Environment - Several studies report difficulties in quantifying chlorinated paraffins, leading to uncertain concentrations in the different environmental media. Furthermore, neither SCCPs nor MCCPs are integrated in a regular Danish monitoring programme. Therefore, it is very scattered, and temporal comparisons of study results are uncertain and do not allow for distinct conclusions about historical development of environmental concentrations, or effects of control measures. Consistent future monitoring data might reveal to what extent the recent restriction on use and production of SCCPs influences environmental concentrations. Furthermore, it should be regarded as important to follow the development of environmental concentrations of MCCPs, since they might substitute for SCCPs in certain applications.

The PBT-properties of MCCPs are currently being considered under the Substance Evaluation procedure of the REACH Regulation. As MCCPs are multi-constituent mixtures, there are uncertainties regarding both the persistence and bioaccumulation potential for MCCPs and further information is needed in order to conclude on whether or not the substance meets the P or B criteria.

Data for the further assessment of the significance of long-range transport of SCCPs and MCCPs and effects in remote areas are needed.

Human health – The underlying mechanism of male rat kidney carcinogenesis and the relevance of the observed tumours for human health still need further clarification in order to draw firm conclusions regarding the toxicity of the chlorinated paraffins and the significance of the different chain length and degree of chlorination.

TDIs have not been established by EFSA for SCCPs and MCCPs, and there is a need for further assessment of the exposure levels vs. TDI.

As well, possible endocrine disrupting effects need further clarification.

Alternatives - A number of challenges regarding the identification of alternatives to MCCPs in the relevant applications above should be considered:

- Findings are mainly available from reports, reviews and studies as well as marketing material based on SCCPs, as regulation is in force for these.
- Only limited information is available, and therefore, much information for the specific applications is obtained from just one or very few sources, which may leave some uncertainty about the conclusions.
- Marketing material and information obtained directly from approaching companies may be subjective and biased.
- Much of the obtained information is based on anticipated alternatives, while quite a few technical tests and corresponding assessments of performance as well as environmental and toxicological aspects have been considered thoroughly for this study.

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Appendix 1: Abbreviation and acromyns

AMAP	Arctic Monitoring and Assessment Programme
ASE	Sulfonic acids, C10 – C18-alkane, phenylesters
BAT	Best Available Techniques
BBP	Butyl benzyl phthalate
BCF	Bioconcentration factor
BMF	Biomagnification factor
CEFIC	European Chemical Industry Council
CLP	Classification, Labelling and Packaging (Regulation)
CMR	Carcinogenic, mutagenic or toxic to reproduction
COHIBA	Control of hazardous substances in the Baltic Sea region
COMGHA	Mixture of 12-(acetoxy)-stearic acid, 2,3-bis(acetoxy)propyl ester and 0ctadecanoic acid, 2,3-(bis(acetoxy)propyl ester
CPs	Chlorinated paraffins
DCE	Danish Centre for Environment and Energy
DEFRA	Department for Environment, Food and Rural Affairs (UK)
DEGD	Diethylene glycol dibenzoate
DEHP	Bis(2-ethylhexyl) phthalate
DEHT	Di (2-ethyl-hexyl) terephthalate
DFL	Danmarks Farve- og Limindustri
DGD	Dipropylene glycol dibenzoate
DIDP	Di-"isodecyl" phthalate
DINP	Di- "isononyl" phthalate
DINA	Di-2-ethylhexyl adipate
DINCH	Di-isononyl-cyclohexane-1,2dicarboxylate
DPHP	di-2-propylheptyl phthalate
EASE	Estimation and Assessment of Substance Exposure
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
ESIS	European Chemical Substances Information System
ETRMA	European Tyre & Rubber Manufacturers' Association
EU	European Union
EU-25	European Union with 25 Member States (Today the EU has 28 Member States)
FEICA	Association of the European Adhesive & Sealant Industry
HELCOM	The Baltic Marine Environment Protection Commission (Helsinki Commission)
HFFR	Halogen-free flame retardant
IPCS	International Programme on Chemical Safety
LCCPs	Long-chain chlorinated paraffins (C>18)
LOUS	List of Undesirable Substances (of the Danish EPA)
LSFOH	Low-smoke free of-halogen
MCCPs	Medium chain chlorinated paraffins (C14-17)
MOS	Margin of safety
MSWI	Municipal solid waste incinerators
MWF	Metal working fluid
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration
NOVANA	Danish national monitoring and assessment programme
OECD	Organisation for Economic Co-operation and Development
OSPAR	Convention for the Protection of the Marine Environment of the North-East Atlantic

PBT	Persistent, bioaccumulative and persistent
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
POPRC	Persistent Organic Pollutants Review Committee
POPs	Persistent Organic Pollutants
PRTR	Pollutant Release and Transfer Register
PVC	Polyvinyl chloride
RAR	Risk Assessment Report
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation)
SCCPs	Short chain chlorinated paraffins (C10-13)
SCHER	Scientific Committee on Health and Environmental Risks
SOCOPSE	Source control of priority substances in Europe (a project)
SPT	Association of Danish Cosmetics, Toiletries, Soap and Detergent Industries
SVHC	Substance of Very High Concern
TDI	Tolerable daily intake
TMF	Trophic magnification factor
TSH	Thyroid stimulating hormone
UBA	Umweltbundesamt (Germany)
vBvP	Very bioaccumulative and very persistent

Appendix 2: Background information to chapter 2 on legal framework

The following annex provides some background information on subjects addressed in Chapter 2. The intention is that the reader less familiar with the legal context may read this concurrently with chapter 2.

EU and Danish legislation
Chemicals are regulated via EU and national legislations, the latter often being a national transposition of EU directives.

There are four main EU legal instruments:

- Regulations (DK: Forordninger) are binding in their entirety and directly applicable in all EU Member States.
- Directives (DK: Direktiver) are binding for the EU Member States as to the results to be achieved. Directives have to be transposed (DK: gennemført) into the national legal framework within a given timeframe. Directives leave a margin for manoeuvring as to the form and means of implementation. However, there are great differences in the space for manoeuvring between directives. For example, several directives regulating chemicals previously were rather specific and often transposed more or less word-by-word into national legislation. Consequently, and to further strengthen a level playing field within the internal market, the new chemicals policy (REACH) and the new legislation for classification and labelling (CLP) were implemented as Regulations. In Denmark, Directives are most frequently transposed as laws (DK: love) and statutory orders (DK: bekendtgørelser).

The European Commission has the right and the duty to suggest new legislation in the form of regulations and directives. New or recast directives and regulations often have transitional periods for the various provisions set out in the legal text. In the following, we will generally list the latest piece of EU legal text, even if the provisions identified are not yet fully implemented. On the other hand, we will include currently valid Danish legislation, e.g. the implementation of the cosmetics directive) even if this will be replaced with the new Cosmetic Regulation.

- Decisions are fully binding on those to whom they are addressed. Decisions are EU laws relating to specific cases. They can come from the EU Council (sometimes jointly with the European Parliament) or the European Commission. In relation to EU chemicals policy, decisions are e.g. used in relation to inclusion of substances in REACH Annex XVII (restrictions). This takes place via a "comitology procedure" involving Member State representatives. Decisions are also used under the EU ecolabelling Regulation in relation to establishing ecolabelling criteria for specific product groups.
- Recommendations and opinions are non-binding, declaratory instruments.

In conformity with the transposed EU directives, to some extent Danish legislation regulate chemicals via various general or sector specific legislation, most frequently via statutory orders (DK: bekendtgørelser).

Chemicals legislation
REACH and CLP
The REACH Regulation[14] and the CLP Regulation[15] are the overarching pieces of EU chemicals legislation regulating industrial chemicals. The below will briefly summarise the REACH and CLP

[14] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

[15] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

provisions and give an overview of 'pipeline' procedures, i.e. procedures which may (or may not) result in an eventual inclusion under one of the REACH procedures.

(Pre-)Registration
All manufacturers and importers of chemical substances > 1 tonne/year have to register their chemicals with the European Chemicals Agency (ECHA). Pre-registered chemicals benefit from tonnage and property dependent staggered deadlines:

- 30 November 2010: Registration of substances manufactured or imported at 1000 tonnes or more per year, carcinogenic, mutagenic or toxic to reproduction substances above 1 tonne per year, and substances dangerous to aquatic organisms or the environment above 100 tonnes per year.
- 31 May 2013: Registration of substances manufactured or imported at 100-1000 tonnes per year.
- 31 May 2018: Registration of substances manufactured or imported at 1-100 tonnes per year.

Evaluation
A selected number of registrations will be evaluated by ECHA and the EU Member States. Evaluation covers assessment of the compliance of individual dossiers (dossier evaluation) and substance evaluations involving information from all registrations of a given substance to see if further EU action is needed on that substance, for example as a restriction (substance evaluation).

Authorisation
Authorisation aims at substituting or limiting the manufacturing, import and use of substances of very high concern (SVHC). For substances included in REACH annex XIV, industry has to cease use of those substance within a given deadline (sunset date) or apply for authorisation for certain specified uses within an application date.

Restriction
If the authorities assess that that there is a risk to be addressed at the EU level, limitations of the manufacturing and use of a chemical substance (or substance group) may be implemented. Restrictions are listed in REACH annex XVII, which has also taken over the restrictions from the previous legislation (Directive 76/769/EEC).

Classification and Labelling
The CLP Regulation implements the United Nations Global Harmonised System (GHS) for classification and labelling of substances and mixtures of substances into EU legislation. It further specifies rules for packaging of chemicals.

Two classification and labelling provisions are:

1. **Harmonised classification and labelling** for a number of chemical substances. These classifications are agreed at the EU level and can be found in CLP Annex VI. In addition to newly agreed harmonised classifications, the annex has taken over the harmonised classifications in Annex I of the previous Dangerous Substances Directive (67/548/EEC); classifications which have been 'translated' according to the new classification rules.

2. **Classification and labelling inventory**. All manufacturers and importers of chemicals substances are obliged to classify and label their substances. If no harmonised classification is available, a self-classification shall be done based on available information according to the classification criteria in the CLP regulation. As a new requirement, these self-classifications should be notified to ECHA, which in turn publishes the classification and labelling inventory based on all notifications

received. There is no tonnage trigger for this obligation. For the purpose of this report, self-classifications are summarised in Appendix 6 to the main report.

Ongoing activities - pipeline

In addition to listing substances already addressed by the provisions of REACH (pre-registrations, registrations, substances included in various annexes of REACH and CLP, etc.), the ECHA website also provides the opportunity for searching for substances in the pipeline in relation to certain REACH and CLP provisions. These will be briefly summarised below:

Community Rolling Action Plan (CoRAP)

The EU Member States have the right and duty to conduct REACH substance evaluations. In order to coordinate this work among Member States and inform the relevant stakeholders of upcoming substance evaluations, a Community Rolling Action Plan (CoRAP) is developed and published, indicating when and by whom a given substance is expected to be evaluated.

Authorisation process; candidate list, Authorisation list, Annex XIV

Before a substance is included in REACH Annex XIV and therefore subject to Authorisation, it has to go through the following steps:

1. It has to be identified as a SVHC leading to inclusion in the candidate list16
2. It has to be prioritised and recommended for inclusion in ANNEX XIV (These can be found as Annex XIV recommendation lists on the ECHA web-site)
3. It has to be included in REACH Annex XIV following a comitology procedure decision (substances on Annex XIV appear on the Authorisation list on the ECHA web-site).

The candidate list (substances agreed to possess SVHC properties) and the Authorisation list are published on the ECHA web-site.

Registry of intentions

When EU Member States and ECHA (when required by the European Commission) prepare a proposal for:

- a harmonised classification and labelling,
- an identification of a substance as SVHC, or
- a restriction.

This is done as a REACH Annex XV proposal.

The 'registry of intentions' gives an overview of intentions in relation to Annex XV dossiers divided into:

- current intentions for submitting an Annex XV dossier,
- dossiers submitted, and
- withdrawn intentions and withdrawn submissions

for the three types of Annex XV dossiers.

International agreements

OSPAR Convention

OSPAR is the mechanism by which fifteen Governments of the western coasts and catchments of Europe, together with the European Community, cooperate to protect the marine environment of the North-East Atlantic.

[16] It should be noted that the candidate list is also used in relation to articles imported to, produced in or distributed in the EU. Certain supply chain information is triggered if the articles contain more than 0.1% (w/w) (REACH Arcticle 7.2 ff).

Work to implement the OSPAR Convention and its strategies is taken forward through the adoption of decisions, which are legally binding on the Contracting Parties, recommendations and other agreements. Decisions and recommendations set out actions to be taken by the Contracting Parties. These measures are complemented by other agreements setting out:

- issues of importance;
- agreed programmes of monitoring, information collection or other work which the Contracting Parties commit to carry out;
- guidelines or guidance setting out the way that any programme or measure should be implemented, and
- actions to be taken by the OSPAR Commission on behalf of the Contracting Parties.

HELCOM - Helsinki Convention

The Helsinki Commission, or HELCOM, works to protect the marine environment of the Baltic Sea from all sources of pollution through intergovernmental co-operation between Denmark, Estonia, the European Community, Finland, Germany, Latvia, Lithuania, Poland, Russia and Sweden. HELCOM is the governing body of the "Convention on the Protection of the Marine Environment of the Baltic Sea Area" - more usually known as the Helsinki Convention.

In pursuing this objective and vision the countries have jointly pooled their efforts in HELCOM, which works as:

- an environmental policy maker for the Baltic Sea area by developing common environmental objectives and actions;
- an environmental focal point providing information about (i) the state of/trends in the marine environment; (ii) the efficiency of measures to protect it and (iii) common initiatives and positions which can form the basis for decision-making in other international fora;
- a body for developing, according to the specific needs of the Baltic Sea, Recommendations of its own and Recommendations supplementary to measures imposed by other international organisations;
- a supervisory body dedicated to ensuring that HELCOM environmental standards are fully implemented by all parties throughout the Baltic Sea and its catchment area; and
- a co-ordinating body, ascertaining multilateral response in case of major maritime incidents.

CLRTAP - Convention on Long-range Transboundary Air Pollution

Since 1979 the Convention on Long-range Transboundary Air Pollution (CLRTAP) has addressed some of the major environmental problems of the UNECE (United Nations Economic Commission for Europe) region through scientific collaboration and policy negotiation.

The aim of the Convention is that Parties shall endeavour to limit and, as far as possible, gradually reduce and prevent air pollution including long-range transboundary air pollution. Parties develop policies and strategies to combat the discharge of air pollutants through exchanges of information, consultation, research and monitoring.

The Convention has been extended by eight protocols that identify specific measures to be taken by Parties to cut their emissions of air pollutants. Three of the protocols specifically address the emission of hazardous substances of which some are included in LOUS:

- The 1998 Protocol on Persistent Organic Pollutants (POPs); 33 Parties. Entered into force on 23 October 2003.
- The 1998 Protocol on Heavy Metals; 33 Parties. Entered into force on 29 December 2003.

- The 1991 Protocol concerning the Control of Emissions of Volatile Organic Compounds or their Transboundary Fluxes; 24 Parties. Entered into force 29 September 1997.

Stockholm Convention on Persistent Organic Pollutants (POPs)
The Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of humans and wildlife, and have adverse effects to human health or to the environment. The Convention is administered by the United Nations Environment Programme and is based in Geneva, Switzerland.

Rotterdam Convention – PIC Convention
The objectives of the Rotterdam Convention are:
- to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm;
- to contribute to the environmentally sound use of those hazardous chemicals, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties.
- The Convention creates legally binding obligations for the implementation of the Prior Informed Consent (PIC) procedure. It built on the voluntary PIC procedure, initiated by UNEP and FAO in 1989 and ceased on 24 February 2006.

The Convention covers pesticides and industrial chemicals that have been banned or severely restricted for health or environmental reasons by Parties and which have been notified by Parties for inclusion in the PIC procedure. One notification from each of two specified regions triggers consideration of addition of a chemical to Annex III of the Convention. Severely hazardous pesticide formulations that present a risk under conditions of use in developing countries or countries with economies in transition may also be proposed for inclusion in Annex III.

Basel Convention
The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal was adopted on 22 March 1989 by the Conference of Plenipotentiaries in Basel, Switzerland, in response to a public outcry following the discovery, in the 1980s, in Africa and other parts of the developing world of deposits of toxic wastes imported from abroad.

The overarching objective of the Basel Convention is to protect human health and the environment against the adverse effects of hazardous wastes. Its scope of application covers a wide range of wastes defined as “hazardous wastes” based on their origin and/or composition and their characteristics, as well as two types of wastes defined as “other wastes” - household waste and incinerator ash.

The provisions of the Convention center around the following principal aims:

- the reduction of hazardous waste generation and the promotion of environmentally sound management of hazardous wastes, wherever the place of disposal;
- the restriction of transboundary movements of hazardous wastes except where it is perceived to be in accordance with the principles of environmentally sound management, and
- a regulatory system applying to cases where transboundary movements are permissible.

Eco-labels
Eco-label schemes are voluntary schemes where industry can apply for the right to use the eco-label on their products if these fulfil the ecolabelling criteria for that type of product. An EU scheme (the

flower) and various national/regional schemes exist. In this project we have focused on the three most common schemes encountered on Danish products.

EU flower
The EU ecolabelling Regulation lays out the general rules and conditions for the EU ecolabel; the flower. Criteria for new product groups are gradually added to the scheme via 'decisions'; e.g. the Commission Decision of 21 June 2007 establishing the ecological criteria for the award of the Community eco-label to soaps, shampoos and hair conditioners.

Nordic Swan
The Nordic Swan is a cooperation between Denmark, Iceland, Norway, Sweden and Finland. The Nordic Ecolabelling Board consists of members from each national Ecolabelling Board and decides on Nordic criteria requirements for products and services. In Denmark, the practical implementation of the rules, applications and approval process related to the EU flower and Nordic Swan is hosted by Ecolabelling Denmark "Miljømærkning Danmark" (http://www.ecolabel.dk/). New criteria are applicable in Denmark when they are published on the Ecolabelling Denmark's website (according to Statutory Order no. 447 of 23/04/2010).

Appendix 3: Physical/chemical properties of SCCPs

TABLE 46
ENVIRONMENTALLY RELEVANT PHYSICAL PROPERTIES OF SCCP CONGENERS AND MIXTURES OF ISOMERS (POPRC, 2010)

SCCP congener	% Cl	Vapour pressure (Pa)	Henry's law constant (Pa•m3/mol)	Water solubility (μg/l)	log K_{OW} 1	log K_{OA} 1
$C_{10}H_{18}Cl_4$	50	0.028	17.7	328, 630, 2370	5.93	8.2
$C_{10}H_{17}Cl_5$	56	0.0040–0.0054	2.62–4.92	449–692	–	8.9–9.0
$C_{10}H_{16}Cl_6$	61	0.0011–0.0022	–	–	–	–
$C_{10}H_{13}Cl_9$	71	0.00024	–	400	5.64	–
$^{14}C_{11}$	59	–	–	150	–	–
$C_{11}H_{20}Cl_4$	48	0.01	6.32	575	5.93	8.5
$C_{11}H_{19}Cl_5$	54	0.001–0.002	0.68–1.46	546–962	6.20–6.40	9.6–9.8
$C_{11}H_{18}Cl_6$	58	0.00024–0.0005	–	–	6.40	–
$C_{11.5}$	60	–	–	–	4.48–7.38	–
$^{14}C_{12}H_{21}Cl_5$	51	0.0016–0.0019	1.37	–	–	–
$C_{12}H_{20}Cl_6$	56	–	–	–	6.61	–
$^{14}C_{12}H_{20}Cl_6$	56	0.00014–0.00052	–	–	6.2	–
$C_{12}H_{19}Cl_7$	59	–	–	–	7.00	–
$C_{12}H_{18}Cl_8$	63	–	–	–	7.00	–
$C_{12}H_{16}Cl_{10}$	67	–	–	–	6.6	–
$C_{13}H_{23}Cl_5$	49	0.00032	–	78	6.14	9.4
$C_{13}H_{22}Cl_6$	53	–	–	–	6.77–7.00	–
$C_{13}H_{21}Cl_7$	58	–	–	–	7.14	–
$C_{13}H_{16}Cl_{12}$	70	2.8 × 10–7	–	6.4	7.207	–
C_{10-13}	49	–	–	–	4.39–6.93	–
C_{10-13}	63	–	–	–	5.47–7.30	–
C_{10-13}	70	–	–	–	5.68–8.69	–
C_{10-13}	71	–	–	–	5.37–8.69	–

1 Octanol–air partition coefficient calculated from KOW/KAW, where KOW is the octanol–water partition coefficient and KAW is the air–water partition coefficient or unitless Henry's law constant (KAW = HLC/RT, where HLC = Henry's law constant, R = gas constant 8.319 Pa•m3/mol K–1 and T = 293 K).

Survey of short-chain and medium-chain chlorinated paraffins

This survey is part of the Danish EPA's review of the substances on the List of Undesirable Substances (LOUS). The report presents information on the use and occurrence of the short-chain and medium-chain chlorinated paraffins, internationally and in Denmark, information on environmental and health effects, releases and fate, exposure and presence in humans and the environment, on alternatives to the substances, on existing regulation, waste management and information regarding ongoing activities under REACH, among others.

Kortlægning af kortkædede og langkædede chlorparaffiner

Denne kortlægning er et led i Miljøstyrelsens kortlægninger af stofferne på Listen Over Uønskede Stoffer (LOUS). Rapporten indeholder blandt andet en beskrivelse af brugen og forekomsten af kortkædede og mellemkædede chlorparaffiner, internationalt og i Danmark, en beskrivelse af miljø- og sundhedseffekter af stofferne, udslip og skæbne, eksponering og forekomst i mennesker og miljø, viden om alternativer, eksisterende regulering, affaldsbehandling og igangværende aktiviteter under REACH.

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