THIS DOCUMENT HAS BEEN PREPARED ACCORDING TO THE PROVISIONS OF ARTICLE 136(3) “TRANSITIONAL MEASURES REGARDING EXISTING SUBSTANCES” OF REACH (REGULATION (EC) 1907/2006). IT IS NOT A PROPOSAL FOR A RESTRICTION ALTHOUGH THE FORMAT IS THE SAME

ANNEX XV RESTRICTION REPORT

SUBMITTED BY: United Kingdom
DATE: 30th November 2008

SUBSTANCE NAME: Medium chain chlorinated paraffins (MCCPs)
IUPAC NAME: Alkanes, C_{14-17}, chloro
EC NUMBER: 287-477-0
CAS NUMBER: 85535-85-9

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A. PROPOSAL

A.1 Proposed restriction(s)

A restriction on the marketing and use of medium-chain chlorinated paraffins (MCCPs) in leather fat liquors was agreed at the 15th Risk Reduction Strategy meeting. Although the restriction was agreed it was not endorsed. Therefore, the proposed restriction for use of MCCPs in leather fat liquoring will not be discussed further within this Annex XV dossier but will be taken forward, within the REACH process, by UK Government.

No further restrictions on the manufacture or use of MCCPs are proposed within this Annex XV report.

A.1.1 The identity of the substance

Chemical Name:	Medium chain chlorinated paraffins
EC Number:	287-477-0
CAS Number:	85535-85-9
IUPAC Name:	Alkanes, C_{14-17}, chloro

A.2 Background to the transition dossier

A.2.1 Human Health

The human health assessment of medium-chain chlorinated paraffins (MCCPs) was evaluated and agreed (2005) under the Existing Substances Regulations (ESR) (793/93/EEC).

Whenever a conclusion (iii) was assigned under the ESR a risk reduction strategy was developed. A conclusion (iii) denotes that further risk management measures (RMMs) are required to control the risk. As ESR has been repealed by REACH (Registration, Evaluation and Authorisation of Chemicals) an Annex XV Restriction document has to be developed for this transitional substance. This Annex XV report **only** examines those human health scenarios that were assigned a conclusion (iii) following the update to the human health part of the risk assessment report (RAR) in 2008. This Annex XV report **will not** revisit any other conclusions made in the RAR.

The RAR concluded that:

1. Workers

There is a need for reducing the risks (conclusion iii) from workers exposed to MCCPs during oil-based metal working fluid (MWF) use. The calculated margins of safety for this scenario in relation to repeated dose toxicity, carcinogenicity, effects mediated via lactation and effects at the time of parturition are unacceptably low.

For all other scenarios (use as a plasticiser, use as a flame retardants, use of water-based MWFs, fat liquors for leather, carbonless copy paper) there were no human health effects which lead to a conclusion (iii) in the RAR for workers. Therefore, no further risk management activity under REACH is required.

2. Consumers

There were no human health effects which lead to a conclusion (iii) in the RAR for consumers. Therefore, no further risk management activity under REACH is required.

3. Exposure via the environment

There were no human health effects which lead to a conclusion (iii) in the RAR for exposure via the environment. Therefore, no further risk management activity under REACH is required.

This Annex XV report contains some of the information given in the 2005 RAR. However, for full details reference should be made to the RAR and its update. The updated RAR has not yet been published on the website of the European Chemicals Bureau (ECB) and will therefore be presented with this Annex XV report for information purposes only.

A2.2 Environment

An environmental Risk Reduction Strategy (RRS) (February, 2008) for uses of MCCPs, that had a conclusion (iii) following the RAR (2005) and its environmental update in 2007, was discussed at the 15th Risk Reduction Strategy meeting in 2008.

The proposals presented in the environmental RRS are outlined in Table 1.1.

Table 1.1 Original proposals (as presented at the 15th Risk Reduction Strategy Meeting) for limiting the risks associated with the use of MCCPs

Use	Marketing and Use	Integrated Pollution Prevention and Control	Water Framework Directive	Waste oils	No additional measures
Formulation and use of metal cutting/working fluids		✓	✓	✓	
Use in leather fat liquors	✓				
Use in Polyvinyl chloride (PVC) compounding and conversion		✓	✓		
Use in conversion of rubber and polymers other than PVC			✓		
Recycling of Carbonless copy paper		✓	✓		
Waste remaining in the environment					✓

The majority of the environmental RRS was agreed at the 15th Risk Reduction Strategy meeting, with the proposal for restricting the use of MCCPs in leather fat liquors being agreed at the meeting (see section A.1). No further discussion on the use of MCCPs in leather fat liquors will occur within this Annex XV dossier, as this restriction proposal will be taken forward by UK Government.

However, the extent of the proposed measures to reduce environmental exposure for other uses of MCCPs was questioned by several Member States, who indicated a need for precautionary action to be taken given the current uncertainties regarding the persistent, bioaccumulative and toxic (PBT) status of MCCPs. They suggested that further restrictions would be appropriate, particularly for metalworking fluids and PVC (EC, 2008).

Following the risk reduction strategy meeting, additional information was requested by the UK Government (Department of Environment, Food and Rural Affairs (Defra)) from attendees of the meeting to support their suggestions that wider restrictions were appropriate. A number of organisations (including Member States and Industry) have provided additional information and/or comments following discussion of the original RRS (February, 2008).

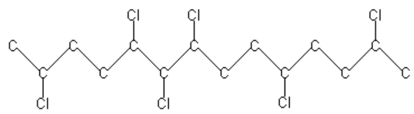
The UK has updated (November, 2008) the environmental RRS to reflect the outcome of the discussion at the 15th Risk Reduction Strategy Meeting and the further information received from Member States and Industry. This updated (November, 2008) report is attached to this Annex XV report as Annex 1. A very brief summary of the information outlined in Annex 1 is presented in the relevant sections of this Annex XV report.

B. INFORMATION ON HAZARD AND RISK

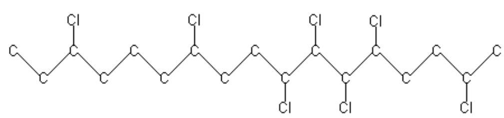
B.1 Identity of the substance(s) and physical and chemical properties

B.1.1 Name and other identifiers of the substance(s)

Chemical Name:	Medium chain chlorinated paraffins
EC Number:	287-477-0
CAS Number:	85535-85-9
IUPAC Name:	Alkanes, C_{14-17}, chloro
Common names:	Chlorinated paraffin (C14-17), chloroalkanes, C14-17; chloroparaffin, medium-chain chlorinated paraffins
Molecular formula:	$C_XH_{(2X-Y+2)}\ CL_Y$, where x=14-17 and y=1-17
Example structural formula	



$C_{14}H_{24}Cl_6$



$C_{17}H_{29}Cl_7$

Molecular weight See Table 1.2

B.1.2 Composition of the substance(s)

B.1.2.1 Purity

The theoretical percentage chlorine content by weight of several compounds that can be considered as MCCPs is presented in Table 1.2. The amount of chlorine (Cl) present in the commercial products is usually expressed as a percentage by weight (% wt. Cl); however, since the commercial products contain a number of components with different carbon chain lengths, it is not possible to identify exactly which compounds are present in a given product, although Table 1.2 can be used as a guide. Wherever possible in this report, the actual carbon chain length (or range of chain length) and the degree of chlorination (% wt. Cl) will be given.

MCCPs are produced commercially with between 40% and 70% chlorine by weight; however, the highest chlorine content normally available is around 58-60% wt. The lowest is around 40% wt. Cl. The majority of the tonnage of MCCPs on the market has Cl content between 45% and 52% (RAR, 2008).

The purity of the produced chlorinated paraffin is related to the purity of the n-paraffin feedstock. In Western Europe, chlorinated paraffins are made from purified n-paraffin feedstocks containing no more than 1-2% isoparaffins and <100 mg aromatics/kg (the aromatics are removed by treatment of the n-paraffin with sulphuric acid). For some high-stability applications, n-paraffin fractions with <1% isoparaffins and <10-100 mg aromatics/kg are used (BUA, 1992).

Table 1.2 Theoretical chlorine content of some MCCPs

Formula	**Molecular weight**	**% Cl by weight**	**Formula**	**Molecular weight**	**% Cl by weight**	**Formula**	**Molecular weight**	**% Cl by weight**
Formula	232.5	15.3	$C_{15}H_{24}Cl_8$	488.0	58.2	$C_{16}H_{18}Cl_{16}$	778.0	73.0
$C_{14}H_{27}Cl_3$	301.5	35.3	$C_{15}H_{20}Cl_{12}$	626.0	68.1			
$C_{14}H_{24}Cl_6$	405.0	52.6	$C_{15}H_{17}Cl_{15}$	729.5	73.0	$C_{17}H_{35}Cl$	274.5	12.9
$C_{14}H_{21}Cl_9$	508.5	62.8				$C_{17}H_{32}Cl_4$	378.0	37.6
$C_{14}H_{18}Cl_{12}$	612.0	69.6	$C_{16}H_{33}Cl$	260.5	13.6	$C_{17}H_{29}Cl_7$	481.5	51.6
$C_{14}H_{16}Cl_{14}$	681.0	73.0	$C_{16}H_{30}Cl_4$	364.0	39.0	$C_{17}H_{26}Cl_{10}$	585.0	60.7
			$C_{16}H_{27}Cl_7$	467.5	53.2	$C_{17}H_{23}Cl_{13}$	688.5	67.0
$C_{15}H_{31}Cl$	246.5	14.4	$C_{16}H_{24}Cl_{10}$	571.0	62.2	$C_{17}H_{21}Cl_{15}$	757.5	70.3
$C_{15}H_{28}Cl_4$	350.0	40.6	$C_{16}H_{21}Cl_{13}$	674.5	68.4	$C_{17}H_{19}Cl_{17}$	826.5	73.0

No specific analytical methods are currently available for the detection of possible impurities present in the commercial products (ICI, 1995). However, any impurities present in the commercial chlorinated paraffins are likely to be related to those present in the n-paraffin feedstock, in which the major non-paraffinic impurity is a small proportion of aromatics (generally in the range 50-100 ppm). The levels of chlorinated paraffins of chain lengths other than C_{14-17} present in the current commercial products are <1%. The producers of MCCPs (represented by Euro Chlor) have, since 1991, used paraffin feedstocks in the production process with a C_{10-13} content of <1% (the actual levels are often much lower than this), and a >C_{18} content of <1% (RAR, 2008).

B.1.2.2 Additives

It is known that additives/stabilisers such as long-chain epoxidised soya oil or glycidyl ether are added to some chlorinated paraffins to inhibit the release of hydrogen chloride (HCl) at elevated temperatures. These are used at concentrations of <1% by weight. For some high thermal stability formulations, other additives e.g. organophosphorus compounds have been reported to be used in conjunction with these (BUA, 1992).

B.1.2.3 Medium-chain impurities present in other chlorinated paraffin *products*

It has recently been reported that some long-chain chlorinated paraffins based on a C_{18-20} carbon chain length may contain a substantial proportion of C_{17} chlorinated paraffins, with only very small amounts of chlorinated paraffins of shorter chain lengths (RAR, 2008). The typical levels reported were 17% C_{17} and <1% C_{16}, although the range of the C_{17} impurity was given as 10-20%. The amounts of chlorinated paraffins with carbon chain lengths of C_{15} or lower present in the C_{18-20} liquid products would be negligibly small.

B.1.3 Physico-chemical properties

The physico-chemical properties are outlined in Table 1.3.

Table 1.3 Physicochemical properties of some MCCPs

Property	Chlorine content (% wt)	Value	Remarks
Physical state (at ntp)	40-63	Liquid	
Pour point		-45 °C to 25 °C	commercial mixtures - no distinct melting point
Boiling point (at ntp)		>200 °C	decomposition with release of HCl
Density	41	1.095 g/cm^3 at 20 °C	
	56	1.315 g/cm^3 at 20 °C	
	40-58	1.1-1.38 g/cm^3 at 25 °C	
	56	1.28-1.31 g/cm^3 at 60 °C	
Vapour pressure	45	2.27´10^{-3} Pa at 40 °C	
		0.16 Pa at 80 °C	
	52	1.3´10^{-4}-2.7´10^{-4} Pa at 20 °C	
		1.07´10^{-3} Pa at 45 °C	
		6.0´10^{-3} Pa at 60 °C	
		0.051 Pa at 80 °C	
Water solubility		0.005-0.027 mg/l	
Log octanol-water	45	5.52-8.21	measured by a high
partition coefficient	52	5.47-8.01	performance thin layer chromatography method
Flash point	>40	>210 °C	closed cup
Autoflammability		not stated	
Explosivity		not applicable	
Oxidising properties		none	

Note: ntp = normal temperature and pressure.

B.2 Manufacture and uses

B.2.1 Manufacture and import of a substance

As outlined in the environmental RRS (see section 1.2.2 of Annex 1) there were six sites manufacturing MCCPs in the EU in 2004. It is reported in the International Uniform Chemical Information Database (IUCLID) that the sites in the EU produce between 45000 -160000 tonnes of MCCPs per year. In 2006, Euro Chlor (2008b) indicated that 63,691 tonnes of MCCPs were sold in the EU 25.

Details on how MCCPs are manufactured can be found in Section 2.1 of the RAR.

B.2.2 Uses

The uses of MCCPs assigned a conclusion (iii) for human health (oil-based metal working fluids only) or the environment (except leather fat liquors) are outlined in Table 2.1. The usage information was gathered for the RRS (see Annex 1).

Table 2.1 Summary of MCCPs use in the EU (metric tonnes)

Application	1994	1997	2003	2006
Metal working / cutting	2,611	5,953	8,113	8,920
Polyvinyl chloride (PVC)	45,476	51,827	32,450	34,676
Rubber/polymers (other than PVC)	2,497	2,146	3,521	7,077
Carbonless copy paper*	1,296	741	89	-
Total	**56,573**	**65,256**	**53,820**	**63,691**

As can be seen from Table 2.1 and confirmed by industry MCCPs are no longer used in the production of carbonless copy paper. As this use is no longer current it will not be considered further within this Annex XV report (it has been considered in Annex 1).

B.3 Classification and labelling

B.3.1 Classification in Annex I of Directive 67/548/EEC

MCCPs are currently classified (published in the Official Journal in October 2008 and will come into force in 1 June 2009) in Annex 1 of Directive 67/548/EEC (Dangerous Substance Directive) with respect to their effects on human health or the environment as follows.

Environment

<u>Classification</u>: N Dangerous for the environment
<u>Labelling</u>: R50/53

R Phrases:

R50 Very toxic to aquatic organisms
R53 May cause long-term adverse effects in the aquatic environment.

Human health

<u>Classification</u>: R64 : R66
<u>Labelling</u>: R64-66

R Phrases:
R64 May cause harm to breast-fed babies
R66 Repeated exposure may cause skin dryness or cracking
S-phrases:
S1/2 Keep locked up and out of reach of children). [*For use only if sold to the public.]*

B.4 Environmental fate properties

The following text only provides a brief summary of relevant properties. Full details are available in the original ESR risk assessment report (EC, 2005) and its subsequent addendum (ECB, 2007).

B.4.1 Degradation

Hydrolysis is not expected to be a significant degradation process for MCCPs in the environment. An atmospheric half-life of 1-2 days is estimated for reaction with hydroxyl radicals: a value for the rate constant for the reaction (k_{OH}) of 8 x 10^{-12} cm^3 $molecule^{-1}$ s^{-1} is used for the environmental modelling in the risk assessment.

MCCPs are not readily or inherently biodegradable, so a biodegradation rate constant of 0 day^{-1} is used in the risk assessment. There is evidence that some microorganisms may be capable of degrading MCCPs in the environment in acclimated or co-metabolic systems, but it is not possible to estimate a likely environmental degradation half-life from these data. The potential for biodegradation appears to decrease with increasing chlorine content, which implies that the more highly chlorinated products may be more persistent than the less chlorinated ones.

B.4.2 Environmental distribution

A soil organic carbon-water partition coefficient (K_{oc}) of 588,844 l/kg can be estimated using quantitative structure activity relationships and an octanol-water partition coefficient (log K_{ow}) of 7.0. This value is considered to be representative of MCCPs in the risk assessment; although some components of the commercial products may have higher or lower values, all are expected to show a high degree of adsorption onto soil, sediment and suspended sediment.

Fugacity modelling indicates that MCCPs are likely to be mainly associated with the soil and sediment compartments.

A removal rate of 93% by adsorption onto sewage sludge during waste water treatment is used in the risk assessment (based on data for short-chain chlorinated paraffins). There is no removal by volatilisation (vapour pressure = 2.7 x 10^{-4} Pa; water solubility = 0.027 mg/l; Henry's law constant ~4.9 Pa m^3 mol^{-1}) or degradation, so 7% is released to surface water according to the SIMPLETREAT model.

Some components of the commercial products might have properties that may mean that long-range transport via the atmosphere is a possibility.

B.4.3 Bioaccumulation

The highest measured bioconcentration (BCF) value for (freshwater) fish is 1,087 l/kg determined in a flow-through study. This value may be conservative since it is based on analysis of radioactivity, but is assumed to be representative for the commercially supplied substance for the assessment of secondary poisoning in the aquatic food chain (along with and an accumulation factor from food of between 1 and 3 on a lipid basis). BCFs appear to be higher for some species of marine mollusc, but interpretation of these studies is not straightforward (e.g. there is a possibility that the organisms were exposed to undissolved substance or the substance adsorbed to food particles).

Nevertheless, a range of other information (e.g. predictions, dietary accumulation, relatively long elimination half-lives in a number of species, and monitoring studies) suggests that the overall bioaccumulation factor (BAF) might be above 2,000 l/kg for some components. The available database is relatively limited and considerable uncertainty exists over the actual bioaccumulation potential of this type of substance. Further fish bioaccumulation work is being performed to provide a more solid conclusion for this endpoint (results will not be available until after 1 December 2008).

A measured $BCF_{earthworm}$ of 5.6 l/kg on a wet weight basis is used for the assessment of terrestrial secondary poisoning. The potential for uptake by worms from soil (and sediment) appears to reduce with increasing chlorine content.

B.4.4 Secondary poisoning

As described in the preceding paragraphs, the substance is persistent and has a moderately high bioaccumulation factor. Since it is classified with the risk phrase R64, there is a potential for secondary poisoning.

B.5 Human health hazard assessment

Full details of the human health hazard assessment can be found in section 4.1.2 of the EU RAR and its update.

B.5.1 Derivation of DNEL(s)/DMEL(s) or other quantitative or qualitative measure for dose response

The purpose of this transitional dossier is to develop a risk reduction strategy for exposure situations for which conclusion (iii) was reached in the RAR. Therefore, derived no effect levels (DNELs) have only been calculated for the health endpoints and routes of exposure that are relevant to the exposure situations of concern (conclusion iii) identified in the RAR.

B.5.1.1. Overview of dose descriptors

The human health endpoints for which concerns (conclusion iii) have been identified in the RAR are:

- Repeat dose toxicity
- Carcinogenicity
- Effects at the time of parturition
- Effects mediated via lactation

The dose descriptors that were identified in the RAR for these endpoints are summarised in Table 5.1 below.

Table 5.1 Dose descriptors used for risk characterisation in the RAR

Endpoint	Quantitative dose descriptor or other information on potency		Associated relevant effect	Remarks on the study
	Local effect	Systemic effect		
Repeated dose toxicity (sub-acute/sub-chronic/chronic)				
Oral		NOAEL 23 mg/kg/day	Kidney damage	90-day dietary study in the rat
Inhalation	No data available			
Dermal	No data available			
Carcinogenicity				
Oral		NOAEL 23 mg/kg/d	Kidney toxicity (chronic nephritis and tubular pigmentation)	90-day dietary study in the rat
Effects at the time of parturition				
Oral		100 mg/kg/day (NOAEL)	Maternal Vit K deficiency in late pregnancy	1-generation dietary study in the rat, total treatment duration of 11-12 weeks
Effects mediated via lactation				
Oral		47 mg/kg/day (NOAEL)	Neonatal Vit K deficiency mediated, via lactation	1-generation dietary study in the rat, total treatment duration of 11-12 weeks

B.5.1.2 Exposure situations for which a risk reduction strategy is required

In the RAR, conclusion (iii) was identified for:

Workers: Use of MCCPs in oil-based metal working fluids

The pattern of exposure for this use includes long-term repeated exposure by the inhalation and dermal routes. DNELs for short-term exposure scenarios are not required as there are no concerns identified for acute toxicity. The following worker DNELs have been derived:

Worker-DNEL long-term for inhalation route
Worker-DNEL long-term for dermal route

Consumers: No concerns were identified in the RAR

Man via the environment: No concerns were identified in the RAR

B.5.1.3 Worker-DNEL long-term inhalation route

The RAR concluded that long-term repeated exposure to MCCPs has the potential to cause adverse effects in the kidney including carcinogenicity. There are also concerns identified for exposed pregnant worker and their breast-fed babies due to vitamin K deficiency. The dose descriptors for these effects have been derived from oral studies in animals as there are no data available for the inhalation route and in humans. Owing to the different nature of the effects seen and the differences in dose-response relationship, it is necessary to calculate separate endpoint specific DNELs for the kidney toxicity, the effects at time of parturition and the effects mediated via lactation in order to identify the critical long-term DNEL. As the dose descriptors have been identified from oral studies, route-to-route extrapolation will be performed.

B.5.1.3.1 Inhalation DNEL derived for kidney effects/carcinogenicity

Increase in kidney weight, chronic nephritis and renal tubular pigmentation were observed in animals repeatedly exposed to MCCPs at dose levels above 222 mg/kg/d (90-day study in the rat). A NOAEL of 23 mg/kg/d was identified for these effects. There are no specific studies investigating the carcinogenicity potential of MCCPs, but kidney tumours were seen with the related substance, short chain chlorinated paraffins (SCCPs). Although “read across” from SCCPs to MCCPs is not straight forward, it cannot be completely ruled out that this form of kidney toxicity might lead to cancer through a non-genotoxic mode of action. Therefore, the NOAEL for repeated dose effects on the kidney identified from the 90-day study in the rat would also apply for the carcinogenicity endpoint.

In the RAR, absorption of MCCPs following oral and inhalation exposure were considered to be 50% in both humans and animals; therefore, there is no need to adjust the NOAEL for bioavailability when extrapolating from oral to inhalation route. The oral NOAEL is divided by 0.38 m^3/kg bw/8h (default respiratory volume in rat, Table R.8.2 of CSR guidance) to give the corresponding rat inhalation 8h-NOAEC (no-observed adverse effect concentration) of 60.53 mg/m^3. To obtain the starting point for workers, a factor of 0.67 is applied to the NOAEC to account for the differences in inhalation rates between animals at rest and humans involved in light activity.

$$23 \div 0.38 \times 0.67 = 41 \text{ mg/m}^3$$

The corrected dose descriptor is therefore 41 mg/m^3 (8h-TWA).

Assessment factors and DNEL calculation for worker DNEL long-term inhalation systemic effects based on animal NOAEL for kidney toxicity and cancer		
Uncertainties	**AF**	**Justification**
Interspecies differences	2.5	It is not necessary to apply an allometric scaling factor because the starting point has been corrected for differences in respiratory volume and this takes account of differences in metabolic rates. There are no data for MCCPs to quantify other differences between animals and humans that could affect interspecies extrapolation; on this basis, the default factor of 2.5 to account for other species differences will be applied.
Intraspecies differences	5	It is not possible to identify from the available data the potential inter-individual variability in susceptibility to MCCP induced toxicity. The standard default for differences within a worker population is therefore applied.
Differences in duration of exposure	2	It is expected that the severity of effects would increase with duration. Since the dose descriptor is derived from a 90-day study, it is necessary to apply a factor of 2 to take account of extrapolation of subchronic data to chronic exposure.
Dose response and endpoint specific/severity issues	1	The difference between the LOAEL (222 mg/kg/d) and the NOAEL (23 mg/kg/d) is approximately 10-fold and the effect at the LOAEL is only minor; therefore, it is not necessary to apply a factor to take account of this.
Quality of database	1	The repeat dose toxicity of MCCPs has been well studied. Although, there are no data on the carcinogenicity of MCCPs, this is considered to be the consequence of the repeated dose toxicity. Overall, confidence in the database is high, so the standard default assessment factor of 1 is applied.
Overall assessment factor: 25		
Endpoint specific DNEL: 41/25 =1.6 mg/m^3		

B.5.1.3.2 Inhalation DNEL derived for maternal Vit K deficiency in late pregnancy leading to potential adverse effects at the time of parturition

A NOAEL of 100 mg/kg/d has been identified in the RAR for these effects from an oral study in which pregnant female rats were exposed to MCCPs for 11-12 weeks. For inhalation exposure, the rat NOAEL is converted into an inhalatory NOAEC by dividing it with 0.38 m^3/kg bw (the default respiratory volume for the rat corresponding to the daily duration for worker exposure) to give 263.16 mg/m^3 (8h-TWA). In the RAR, absorption of MCCPs following oral and inhalation exposure were considered to be 50% in both humans and animals; therefore, a correction for differences in bioavailability is not needed. To obtain the starting point for workers, a factor of 0.67 is applied to the NOAEC to account for the differences in inhalation rates between animals at rest and humans involved in light activity.

This gives a corrected dose descriptor of 176 mg/m^3 (8h-TWA)

Assessment factors and DNEL calculation for worker DNEL long-term inhalation systemic effects based on the animal NOAEL for Vit K deficiency in the dam		
Uncertainties	**AF**	**Justification**
Interspecies differences	2.5	It is not necessary to apply an allometric scaling factor because the starting point has been corrected for differences in respiratory volume and this takes account of differences in metabolic rates. There are no data for MCCPs to quantify other differences between animals and humans that could affect interspecies extrapolation; on this basis, the default factor of 2.5 to account for other species differences will be applied.
Intraspecies differences	5	It is not possible to identify from the available data the potential inter-individual variability in susceptibility to MCCP induced toxicity. The standard default for differences within a worker population is therefore applied.
Differences in duration of exposure	1	No additional factor to account for differences in duration of exposure is considered necessary as the experimental duration of exposure is the relevant duration of exposure for a working woman of child-bearing capacity.
Dose response and endpoint specific/severity issues	2	16% mortality was observed at the LOAEL (538 mg/kg/d) and given the inadequate spacing between the doses; further adjustment of the dose descriptor by an assessment factor of 2 is consider necessary to account for severity issues.
Quality of database	1	The dose descriptor has been derived from a well-reported guideline-compliant generational study with other studies investigating the possible underlying mechanism also available. The quality of the database is therefore not considered to contribute uncertainty to this assessment and hence it is not necessary to apply an additional factor.
Overall assessment factor: 25		
Endpoint specific DNEL: 176/25 = 7 mg/m^3 (8h-TWA)		

B.5.1.3.3 Inhalation DNEL derived for effects mediated via lactation

A NOAEL of 47 mg/kg bw/d has been identified in the RAR for these effects from a 1-generation fertility study in the rat with total exposure duration of 11-12 weeks. For inhalation exposure, the rat NOAEL is converted into an inhalatory NOAEC by dividing it by 0.38 m^3/kg bw (the default respiratory volume for the rat corresponding to the daily duration for worker exposure) to obtain 123.68

mg/m^3 (8h-TWA). The RAR assumes that absorption via the oral and inhalation routes are equal (i.e. 50%) and to be the same for humans and rats, therefore a correction for differences in bioavailability is not required. To obtain the starting point for workers, a factor of 0.67 is applied to the NOAEC to account for the differences in inhalation rates between animals at rest and humans involved in light activity.

The corrected dose descriptor is 83 mg/m^3 (8h-TWA)

Assessment factors and DNEL calculation for worker DNEL long-term inhalation systemic effects based on the animal NOAEL for effects mediated via lactation		
Uncertainties	**AF**	**Justification**
Interspecies differences	2.5	The dose descriptor is obtained from an inhalation study it is therefore not necessary to apply an allometric scaling factor to take account of differences in basal metabolic rates between animals and humans. There are no data to quantify other differences between animals and humans that could affect interspecies extrapolation. On this basis the default factor of 2.5 to account for other species differences will be applied.
Intraspecies differences	5	It is not possible to identify from the available data the potential inter-individual variability in susceptibility to MCCPs induced toxicity. The standard default for differences within a worker population is therefore applied.
Differences in duration of exposure	1	Subchronic to chronic extrapolation of data is not required, as, for effects via lactation, exposure is not chronic. Hence there is no need to apply an additional factor.
Dose response and endpoint specific/severity issues	2	11% reduction in pup survival was observed at the LOAEL of 74 mg/kg bw/d, although no statistical significance was achieved. Pup survival can vary from 0 to 10% in control (untreated) animals so the effect at the LOAEL is considered to be borderline. However, given that the endpoint of concern is lethality in offspring exposed to MCCPs *in utero*, it is considered appropriate to further adjust the dose descriptor by a factor of 2 to address any residual uncertainty in the dose response.
Quality of database	1	The dose descriptor has been derived from a well-reported guideline-compliant generational study with other studies exploring the possible underlying mechanism also available. The quality of the database is therefore not considered to contribute uncertainty to this assessment and hence it is not necessary to apply an additional factor.
Overall assessment factor: 25		
Endpoint specific DNEL: 83/25 = 3 mg/m^3 (8h-TWA)		

B.5.1.3.4 Selection of worker-DNEL long-term inhalation

Effects of long-term exposure to MCCPs are of different nature; therefore, endpoint specific DNELs have been calculated using animal data. It is therefore necessary to identify which of these DNELs is the critical DNEL for assessing long-term inhalation exposure of workers.

Repeat dose toxicity (i.e. kidney effects) and carcinogenicity were considered together in deriving an endpoint specific DNEL. This is because the cancer would only arise as a result of sustained kidney toxicity, and therefore it seems appropriate to base the risk assessment of both repeated dose effects and cancer on one DNEL (1.6 mg/m^3). Potential adverse effects in exposed pregnant women at the time of parturition and their breast-fed neonates were also considered. Endpoint specific DNELs have been derived separately for the parturition effects (7 mg/m^3) and the lactation-mediated effects (3 mg/m^3); these DNELs are higher than that for the kidney toxicity/carcinogenicity (1.6 mg/m^3).

It is therefore, concluded that the critical DNEL for long-term inhalation exposure in workers is that for repeated dose toxicity/carcinogenicity.

The worker DNEL long-term inhalation route is 1.6 mg/m^3.

B.5.1.4 Worker-DNEL long-term dermal route

MCCPs have the potential to be absorbed across the skin and hence, there is the potential for adverse systemic effects arising as a result of skin exposure. No studies have been undertaken by the dermal route to characterise the dose-response relationship for systemic effects therefore it will be necessary to obtain a long-term dermal DNEL by extrapolation. Since kidney toxicity/carcinogenicity has been identified as the critical health endpoint for long-term inhalation exposure, this endpoint will also be the critical endpoint for long-term dermal exposure. The worker-DNEL long-term dermal route will therefore be based on the animal NOAEL of 23 mg/kg/d obtained from a 90-day study in the rat.

In the RAR, absorption in both humans and animals are considered equal. 1% absorption is assumed for dermal and 50% for the oral routes, respectively; therefore, to conduct a route-to-route extrapolation, there is need to adjust the NOAEL for differences in absorption.

The corrected starting point is therefore:

23 x 50 = 1150 mg/kg/day

Assessment factors and DNEL calculation for worker DNEL long-term dermal systemic effects based on the animal NOAEL		
Uncertainties	**AF**	**Justification**
Interspecies differences	10	The dose descriptor is obtained from an oral study in the rat. To use a value extrapolated from a rat oral study to assess dermal exposure in humans it is necessary to apply an allometric scaling factor of 4 to take account of differences in basal metabolic rates between rats and humans. There are no data for MCCPs to quantify other differences between animals and humans that could affect interspecies extrapolation. On this basis a default factor of 2.5 to account for other species differences will also be applied giving an overall assessment factor of 10.
Intraspecies differences	5	There are no data to quantify variability in susceptibility to the effects of long-term exposure to MCCPs in the human population. The default factor of 5 for workers will therefore be used to take account of intraspecies differences.
Differences in duration of exposure	2	It is expected that the severity of effects would increase with duration. Since the dose descriptor is derived from a 90-day study, it is necessary to apply a factor of 2 to take account of extrapolation of subchronic data to chronic exposure.
Dose response and endpoint specific/severity issues	1	The difference between the LOAEL (222 mg/kg/d) and the NOAEL (23 mg/kg/d) is approximately 10-fold and the effect at the LOAEL is only minor; therefore, it is not necessary to apply a factor to take account of this.
Quality of database	1	The repeat dose toxicity of MCCPs has been well studied. Although, there are no data on the carcinogenicity of MCCPs, this is considered to be the consequence of the repeated dose toxicity. Overall, confidence in the database is high, so the standard default assessment factor of 1 is applied.
Overall assessment factor: 100		
Endpoint specific DNEL: 1150/100 = 11.5 mg/kg/day		

The worker DNEL long-term dermal route is 11.5 mg/kg/day.

B.5.1.5 Summary of critical DNELs

	Worker
DNEL long-term inhalation	1.6 mg/m^3 (8h-TWA)
DNEL long-term dermal	11.5 mg/kg/day

B.6 Human health hazard assessment of physico-chemical properties

A conclusion (ii) for the human health assessment of physico-chemical properties was assigned in the RAR indicating that the risks are adequately controlled.

B.7 Environmental hazard assessment

Full details of the environmental hazard assessment can be found in section 3.2 of the RAR (EC, 2005). Outlined below is a summary of the environmental endpoints that were agreed in the RAR.

B.7.1 Aquatic compartment (including sediment)

The $PNEC_{water}$ is 1 µg/l, based on a 21-day NOEC for *Daphnia magna* and an assessment factor of 10.

The $PNEC_{sediment}$ is 5 mg/kg wet wt., based on a chronic NOEC of 50 mg/kg wet wt. for *Lumbriculus variegatus* and *Hyalella azteca* and an assessment factor of 10.

No PNECs were derived for the marine environment in either EC (2005) or ECB (2007).

B.7.2 Terrestrial compartment

The $PNEC_{soil(standard)}$ is 10.6 mg/kg wet wt., based on a chronic NOEC of 248 mg/kg wet wt. for the worm *Eisenia fetida* – normalised to a $NOEC_{standard}$ of 106 mg/kg wet wt. for a standard soil organic matter/carbon content of 2% (the organic carbon content of the soil used in the worm study was 4.7%) – and an assessment factor of 10.

B.7.3 Atmospheric compartment

No data are available on possible effects of the substance on the atmosphere. However, given the low volatility of the substance, neither biotic nor abiotic effects are likely.

B.7.4 Microbiological activity in sewage treatment systems

The PNEC for waste water treatment plants is estimated to be 80 mg/l, based on the lowest threshold concentration reported to cause effects on bacteria (which approximates to a NOEC/LOEC) and an assessment factor of 10.

B.7.5 Non compartment specific effects relevant for the food chain (secondary poisoning)

In an update to the approach adopted in EC (2005), ECB (2007) derives a $PNEC_{oral}$ of 10 mg/kg food, based on a NOAEL of 300 mg/kg food from a 90-day study with rats and an assessment factor of 30.

B.8 PBT and vPvB assessment

Full details of the PBT assessment can be found in section 3 of the addendum RAR (ECB, 2007). The results of this assessment can be found in section 2.6

of Annex 1. Work on determining the potential PBT properties of MCCPs is still being carried out by industry and is not expected to be complete before 2009.

B.8.1 Assessment of PBT/vPvB properties – Comparison with criteria of Annex XIII

MCCPs meet the screening criterion for P/vP. There are no data from degradation simulation tests with the substance itself. However, the related substance short-chain chlorinated paraffins meets the formal P and vP criteria (EC, 2008), with mineralisation half-lives of around 1,630-1,790 days in freshwater sediment and 335-680 days in marine sediment. These data suggest that MCCPs would also be persistent within the meaning of the PBT criteria and it is considered unlikely that further testing would change this interpretation.

Based on the most reliable Bioaccumulation factor (BCF) estimate of 1,087 l/kg in fish, the substance would not meet the criteria for either B or very bioaccumulative (vB). However, as mentioned in Section B.4.3 above, a number of other factors are relevant and the balance of evidence is that the substance meets the screening criterion for B. Further information on fish bioaccumulation is needed before a final decision can be taken.

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

B.8.2 Emission characterisation

Not relevant for this dossier.

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

B.9.1.1 Summary of existing legal requirements associated with human health

The following discussion of existing legal requirements only details those related to the use of MCCPs in OBMWFs as it was only this that was assigned a conclusion (iii) for human health.

B.9.1.1.1 Regulation 1907/2006 (REACH)

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) will require those companies that manufacture and/or import chemicals in to EU to register them with the European Chemicals Agency (ECHA) in Helsinki. REACH will require these registrations to be supported by data on the substance. The amount and type of data that will be required increases with increasing tonnage.

Registration requires manufacturers and importers to submit:

- a technical dossier, for substances in quantities of 1 tonne or more, and

- a chemical safety report, for substances in quantities of 10 tonnes or more.

The **technical dossier** should contain information on the properties, uses and on the classification of a substance as well as guidance on safe use.

The chemical safety report (CSR) for substances manufactured or imported in quantities starting at 10 tonnes should document the hazards and classification of a substance and the assessment as to whether the substance is PBT or vPvB. When the substance is classified as dangerous or is a PBT or vPvB substance the CSR should also describe exposure scenarios. Exposure scenarios are sets of conditions that describe how substances are manufactured or used during their life-cycle and how the manufacturer or importer controls, or recommends downstream users (DUs) to control, exposures of humans and the environment. The exposure scenarios must include the appropriate risk management measures (RMMs) and operational conditions (OCs) that, when properly implemented, should ensure that the risks from the uses of the substance are adequately controlled. Exposure scenarios should be developed to cover all "identified uses" which are the manufacturers' or importers' own uses, and uses that are made known to the manufacturer or importer by their downstream users and which the manufacturer or importer includes in his assessment. Relevant exposure scenarios will need to be annexed to the safety data sheets that will be supplied to downstream users and distributors.

As all those who manufacture MCCPs in the EU do so in quantities of ≥10 tpa, a CSR will need to be provided by the manufacturer/importer. In addition, as MCCPs will be classified as a dangerous substance, exposure scenarios demonstrating that exposures are below the DNEL will need to be submitted. When a DNEL cannot be derived, (as outlined in Section B5.1) substances should have a qualitative assessment.

The progressive implementation of REACH will have implications for the management of workplace exposure in the EU. Suppliers of substances that fall within the remit of REACH will have to demonstrate that exposures associated with identified uses are less than the DNEL (i.e. that the substance is adequately controlled), and will have to provide information on the measures that should be in place to control exposure (detailed in the CSR and passed onto the supply chain in the safety data sheets).

B.9.1.1.2 Workplace Legislation

The key pieces of EU legislation that govern workplace health and safety are the Framework Directive (89/391/EEC) and its daughter directives including the Chemical Agents Directive (98/24/EC) (CAD). The Framework Directive outlines general principles for the management of workplace health and safety for all workplace hazards. The CAD describes specific measures to be taken in relation to the control of chemical hazards. The CAD requires employers to assess the risks to worker health and safety posed by chemical agents in the workplace and to take the necessary preventative measures to minimise those risks by:

- substitution of a hazardous process or substance with a process or substance which presents no or lower hazards to workers;
- designing work processes and engineering controls to minimise the release of a hazardous chemical agent;
- applying collective protection measures at the source of the risk e.g. adequate ventilation and appropriate organisational measures, and;
- where exposure cannot be prevented by other means, application of individual protection measures including personal protective equipment.

Employers should always, by preference, try to prevent exposure. Where it is not possible to do this, they must control exposure adequately by all routes. The Directive outlines a priority order (as above) in which risk management measures should be applied.

B.9.1.1.3 Occupational Exposure Limit (OEL) Values

The EU has developed a programme whose objectives are to:

- prevent or limit the exposure of workers to dangerous substances at workplaces; and,
- to protect the workers that are likely to be exposed to these substances.

Setting occupational exposure limits is an essential part of this programme, which is endorsed under the following directives:

- Council Framework Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work;
- Council Directive 98/24/EC on the protection of the health and safety of the workers from the risks relating to chemical agents at work (the 'Chemical Agents Directive');
- Commission Directive 2000/39/EC establishing a first list of Indicative Occupational Exposure Limit Values (IOELVs) (for 63 agents) and Commission Directive 2006/15/EC establishing a second list of IOELVs (for 33 agents);
- Council Directive 2004/37/EC on the protection of workers from the risks related to carcinogens or mutagens at work (the Carcinogens and Mutagens Directive).

The major task of the European Commissions's Scientific Committee on Occupational Exposure Limits (SCOEL) is to give advice on the setting of OELs based on scientific data and where appropriate propose values. SCOEL may recommend OELs, which can be supplemented by further notations and information such as routes of absorption, as:

- eight-hour time-weighted average (8hr-TWA);
- short-term exposure limits (STEL); and/or
- biological limit values (BLVs).

SCOEL aims to give health-based OELs that can be recommended when the available scientific data suggest that a clear threshold value can be identified for the adverse effects of the substance in question. For some adverse effects (in particular respiratory sensitisation and genotoxicity i.e. damage to genes), it is currently impossible to identify such limits. In these cases, SCOEL can recommend a pragmatic OEL, which is established on the basis of data on dose and risk.

The European Commission uses the scientific advice from SCOEL to make proposals for IOELVs. Limits based solely on scientific considerations are considered as adaptations to technical progress, and are incorporated in proposals for Commission directives within the framework of the CAD and are indicative. Limits that take account also of socio-economic and technical feasibility factors are included in proposals for Council directives under either CAD or the Carcinogens and Mutagens Directive and are binding.

B.9.1.1.4 Classification and Labelling

Harmonised rules for classification and labelling are outlined in Council Directive 67/548/EEC (Dangerous Substances Directive) and 1999/45/EC (Dangerous Preparations Directive). These Directives will continue alongside the EC Classification, Labelling and Packaging (CLP) Regulations through the transitional period up to June 2015. The CLP Regulation is expected to come into force in January 2009.

The main objective of these Directives is to communicate intrinsic hazardous properties of substances through classification and labelling. The Directives outline the classes of substances or preparations that are considered to be dangerous e.g. sensitisers. The Directives also outline the hazard symbols, risk and safety phrases and labelling and packaging requirements that should be adhered to when a substance is considered to be dangerous.

B.9.1.2 Summary of existing legal requirements associated with the environment

A number of legislative and other measures that are expected to directly or indirectly affect the risks associated with MCCPs have been identified. Detailed information is given on these in Section 3 (see Table 3.1) of Annex 1. These include national level measures taken in the EU Member States and other countries, as well as EU-level legislation such as:

- marketing and use restrictions on SCCPs;
- the Integrated Pollution Prevention and Control Directive;
- the Water Framework Directive, and
- controls on the disposal of waste oils and other chlorinated wastes.

B.9.1.3 Summary of effectiveness of the implemented human health risk management measures

B.9.1.3.1 REACH (1907/2006)

As REACH is a European Regulation, it will be an effective legal instrument to aid MCCPs risk reduction. REACH requires manufacturers and importers to assess the risks that are from the manufacture and/or use of their substance and to pass this information down the supply chain. The information supplied to downstream users will include improved data on the hazards plus an exposure scenario (if one is required depending on whether the substance is classified as dangerous) for the use of the substance in a particular scenario. As MCCPs will be classified as dangerous (see section B.3.1), and are manufactured in quantities ≥10 tpa (see section B.2.1), such information will be available to the user.

This improved information will be passed to the end user after the substance has been registered. MCCPs are manufactured by companies in >1000 tonnes per annum (tpa) and therefore the information should be available to downstream users via safety data sheets from December 2010.

B.9.1.3.2 Chemical Agents Directive (98/24/EC)

If industry applies the principles of ‘good practice’, as outlined by CAD, then this should ensure an effective reduction in exposure of humans to chemical substances in the workplace.

B.9.1.3.3 Indicative Occupational Exposure Limit Values

An OEL is an important tool in exposure control in the workplace. An OEL provides a ‘benchmark’ against which employers can assess the effectiveness of the measures in place to control exposure. In the absence of air monitoring, employers can have no confidence that exposures have been controlled to appropriately low levels and, should employees become ill, they would have no evidence to demonstrate an adequate control regime. Although workplace monitoring can be undertaken in the absence of an OEL, the significance of the concentrations measured/found is often unclear.

Currently, there is no specific EU-wide IOELV or any national OELs in any Member State for MCCPs.

B.9.1.3.4 Classification and Labelling

When substances and preparations are properly classified and labelled the potential hazards are identified and appropriate risk management measures are communicated on labels and in safety data sheets to those handling the substance or preparation. As the classification and labelling of MCCPs has yet to be formally listed in Annex I to Directive 67/548/EEC (as outlined in section 3) then effective communication of these hazards, risks and risk reduction measures are not being fully communicated to the users. For example, once the classification and labelling has been agreed and listed in Annex I then other legislation, such as Directive 92/85/EEC (Pregnant Workers Directive), will also apply.

The Pregnant Workers Directive (92/85/EEC) on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breast feeding places a duty on the employer to temporarily introduce measures for a pregnant or breast-feeding worker to avoid exposure to risk through adjustment of working conditions, granting leave or moving the employee to another job.

It is therefore important that the classification and labelling is agreed to ensure that workers are effectively protected from the hazards of MCCPs.

B.9.1.4 Summary of effectiveness of the implemented environmental risk management measures

Despite the existence of the legislative measures summarised in Section B.9.1.2 (and presented in detail in 3 of Annex 1), there remains a need for limiting the environmental risks associated with MCCPs at the EU-level, given that most of the sectors will generally not be comprehensively regulated in relation to emissions of MCCPs. However, it is recognised that – for most if not all of the sectors – there will be a potentially significant number of companies where emissions are already well controlled and environmental risks will be much lower than those of the worst-case sites covered by the risk assessment.

B.9.2 Manufacturing of MCCPs

A conclusion (ii) was assigned for human health and the environment indicating that there is no need for further risk reduction measures beyond those which are already applied, therefore this scenario will not be discussed any further in this Annex XV report.

B.9.3 Human Health exposure assessment

The information outlined below (in section B.9.3.1) only considers the use of MCCPs in OBMWFs, as this was the only use assigned a conclusion (iii) for human health.

B.9.3.1 Use of oil-based metal working fluids

Introduction

MCCPs are included in oil-based MWF (OBMWF) to enhance lubrication and surface finish in extreme pressure metalworking and forming applications, such as metal cutting and grinding. 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.

As outlined in Table 2.1 more than 8000 tpa of MCCPs were used in the formulation of metal working/cutting fluid in 2006. The amount of chlorinated paraffins present in a given fluid depends on the final application (BUA, 1992). As described in the RAR, OBMWFs products may contain as little as 2% and as high a level as 100% MCCPs. The main uses for OBMWFs are for those containing 5-10% MCCPs. However, some heavy duty applications require OBMWFs with high MCCPs content, typically 50-70% and for processes such as broaching the MCCPs content may be up to 100% (i.e. neat MCCPs). The RAR concluded that a 70 % MCCPs product should be used as representative of heavy-duty processes using MCCPs.

Recent information from one UK-based manufacturer stated that OBMWFs supplied for use in metal removal operations (i.e. cutting and grinding) can contain between 1% and 30% of MCCPs. However, the majority of products by number and volume supplied into the market contain between 5% and 15% MCCPs. These products are used in metal cutting operations such as turning, milling, drilling, boring, tapping, screwing, reaming, gear cutting, form tool work and parting off and in grinding operations. Products with MCCPs content greater than 20% are used for extremely arduous tasks.

In metal forming processes (sometimes known as chip-less machining), MCCPs with higher levels of chlorination are used and are present in the oil at concentrations up to 50% (RAR, 2008). A UK-based manufacturer stated that lubricants supplied for such processes as broaching, pressing, deep drawing, stamping, fine blanking, cold heading, internal thread rolling as well as rod, bar and tube drawing can have MCCPs content ranging from 5-100%, but products typically contain 10-30% MCCPs.

We have assumed that a 10% MCCPs product will be representative of the major processes using MCCPs.

In metal working, MCCPs aerosols may be generated by mechanical agitation during the use of OBMWFs, in particular, in the engineering industry. Oils coming into contact with rapidly rotating machinery would create mist and very low viscosity OBMWFs may also give rise to vapours. Metal forming activities do not give rise to mechanically produced mist. Many thousands are likely to be potentially exposed to MCCPs in their use in MWFs throughout the EU.

<u>Exposure values</u>

Despite a request for industry to provide newer exposure data on the use of MCCPs in OBMWFs for this Annex XV report none were provided. Therefore, the exposure values and approach used in this Annex XV report are those agreed in the RAR.

<u>*Inhalation*</u>

No measured data were available for airborne exposure to MCCPs during its use in OBMWFs. Hence, exposures were derived from measured data on exposure to oil mist. No short-term exposure inhalation values were derived as exposures were considered to be long-term due to the nature of the work.

The RAR described a wide ranging survey of worker exposure to MWFs by the Health and Safety Executive (HSE). A total of 31 sites were surveyed. At 12 of these sites a total of 40 personal exposures to OBMWF were measured. The 95th percentile result of these 40 samples was an 8-hour TWA of 3.4 mg/m^3 for OBMWF. The RAR used 70% as the upper limit of MCCPs content in OBMWFs for major heavy duty applications. This corresponds to a reasonable worst case (RWC) exposure of 2.4 mg/m^3 8-hour TWA (see Table 9.1).

Following the same approach outlined within the RAR a RWC 8-hr TWA has been determined for OBMWFs containing 10 % MCCPs, as it is these concentrations that are typically used within industry. This corresponds to RWC exposure of 0.3 mg/m^3 8-hr TWA for an in-use concentration of 10% (see Table 9.1). No typical inhalation exposure values were detailed in the RAR.

The values outlined above are exposure to liquid droplets containing MCCPs i.e. the MCCPs in liquid form. There will also be some exposure to MCCPs vapour. MCCPs are viscous liquids with very low vapour pressures. A vapour pressure of 2.7 x 10^{-7} KPa at 20°C for the 52% chlorinated MCCPs was used as a representative value for all MCCPs regardless of chlorination in the RAR (see Table 1.2). This vapour pressure corresponds to a saturated vapour concentration (SVC) of 0.051 mg/m^3 (assuming a molecular weight of 450) at 20°C. Thus, personal exposures to MCCPs vapour at ambient temperature in the workplace will be very low, the maximum theoretical vapour concentration being 0.051 mg/m^3. Although processing temperatures are often in excess of 20°C, the temperature of the working environment will usually be about 20°C. Therefore, as outlined above the contribution of the vapour to the total exposure to MCCPs is quite small.

The HSE survey did not include an investigation of exposure to MCCPs in the use of MWFs in metal forming. For this application there may be exposure to mist formed by the condensation of hot vapour. The extent of this will depend upon the extent to which the oil/MCCPs mixture is heated.

The long-term inhalation exposure values used in the risk characterisation are outlined in Table 9.1.

Table 9.1 Reasonable worst-case inhalation exposure to workers using oil-based metal working fluids

MCCPs content in metalworking fluids (%)	RWC exposures (mg/m^3)
10 (major uses)	0.3
70 (heavy duty uses)	2.4

Dermal

Although, there were no specific dermal exposure data to MCCPs in MWFs within the RAR, industry provided estimates of exposure from existing studies on MWFs.

The work by Cherrie (2006) estimated dermal MCCPs exposure in metalworking from a review of three published studies measuring dermal exposure to MWF. In two of the studies (van Wendel de Joode *et al*., 2005 and Roff *et al*., 2004) protective gloves were worn by most of the subjects. As outlined within the RAR, other authors believe that gloves are not commonly worn in this work situation and therefore these studies were considered unsuitable to assess a “real-life” exposure scenario. Therefore, only the study by Semple *et. al*., (2005) was used to assess dermal exposure to MWFs as gloves were not worn.

The study conducted by Semple *et al*., (2005) used wipe sampling to measure dermal exposure to MWF in six engineering firms based in Scotland. No gloves were worn and each hand was sampled separately using moist wipes. The dermal exposure to MWF was highly variable and dependent on the task. From observation of the work practices, four key stages of exposure were identified:

- Machine set-up: Often involved handling drill bits and other tools within theatre of the cutting machine. This was frequently carried out with items that were coated in MWF from previous use.
- Machine operation: Little direct contact with MWF as this was often completely automated. However, in many manual and semi-automated machines the worker moved the MWF nozzle to direct it accurately to the cutting edge which frequently resulted in short but significant whole hand exposure.
- Work piece removal: On completion of the task the cut item still coated with MWF was removed from the tool by the operator with no attempt to remove excess fluid and handling was usually done without gloves.
- Machine/sump maintenance: Dermal exposure occurs during inspection of the sump fluid, removal of excess swarf and general machine maintenance.

Only 16 measurements were available for situations where workers were exposed to OBMWFs and the exposure ranged from 100 to 28,000 mg MWF per hand (front and back). The typical dermal exposure to MWF in this study was estimated as 5,200 mg and the 90th percentile as 36,000 mg.

Using the data from *Semple et al.,* (2005) and assuming a maximum of 70% content of MCCPs in OBMWFs, Cherrie (2006) estimated that the RWC daily dermal MCCPs exposure would be 25,000 mg. This value will be used in the risk characterisation (see Table 9.2).

Following the approach taken within the RAR, typical and RWC exposure values can be determined for an OBMWF containing 10 % MCCPs. A typical value has also been determined for an OBMWF containing 70 % MCCPs. The exposure values taken forward to the risk characterisation are outlined in Table 9.2.

Table 9.2 Typical and Reasonable worst case exposure values for long-term dermal exposure

MCCPs content in metalworking fluids (%)	Exposures (mg/kg/d*)	
	Typical	RWC
10 (major uses)	7	51
70 (heavy duty uses)	52	357

*Based on a 70 kg adult

B.9.4 Summary of environmental exposure assessment

The environmental exposure assessment is described in detail in EC (2005) and ECB (2007), and has not been repeated in this dossier. This section only considers the implications of new information collected during the development of the human health and environmental risk reduction strategies on the following scenarios:

- Use of MCCPs in metal working fluids.
- Use of MCCPs in PVC.

This new information (outlined below) has been used in the update to the RRS (November, 2008), attached as Annex 1.

B.9.4.1 Use of MCCPs in metal working fluids

B.9.4.1.1 New information obtained during consultation on the draft risk reduction strategy

Euro Chlor (2008b) indicates that 63,691 tonnes of MCCPs were sold in the EU 25 in 2006. Of this, 14 % (~8,920 tonnes) were thought to be used in metal working fluids. It is possible that other EU suppliers exist who are not members of Euro Chlor, in which case these figures might be underestimates of the total EU supply to some extent.

A total of 6,681 tonnes of MCCPs were sold in Germany and Austria combined in 2006 with around 17 % of this (~1,140 tonnes) being used in the formulation of metal working fluids (Euro Chlor 2008b). Euro Chlor (2008a) gives a similar figure of around 16% for the percentage of the total use in Germany and Austria that is used in the formulation of metal working fluids.

The total use of MCCPs in Sweden in 2005 was reported to be 94.1 tonnes, with approximately 70 % of this (around 65.8 tonnes) being used in metal working applications (KEMI, 2008). The 2005 usage in this area showed a marked decrease from 2003, where 116 tonnes were used in metal working.

The amount of MCCPs reported to be used in 2005 in the Norwegian Product Register was between 54 and 64 tonnes. Of this, around 5 tonnes (8 %) was reported to be used in lubricants and oils.

As well as this information, two aspects that are, or have been, considered during the development of the Annex XV report for MCCPs (Defra, 2008) need to be taken into account:

- Defra (2008) indicates that if the waste oils legislation (Directive 75/439/EEC[1]) were implemented correctly, the risks to the environment from intermittent release of water-based metalworking fluids are likely to be removed. This clearly has some implications for the environmental risk assessment for this use.

- Section 8.1 of the OECD Emission Scenario Document on Lubricants and Lubricant Additives OECD 2004a) states the following '*This section*

[1] Council Directive 75/439/EEC of 16 June 1975 on the disposal of waste oils. O.J. L 194, 25/07/1975, p. 0023-0025.

considers releases from the sites where cutting fluids are used. The degree to which such releases are important will vary between different countries and to some degree with the size of the operations. In Germany, for example, losses from equipment in use are collected and sent to external treatment sites for disposal. The use of completely encapsulated machine tools helps to make this possible. In these situations, releases from the waste treatment sites will be more significant, and releases from the actual use sites are considered to be negligible.' The UK has proposed a stepwise approach to reducing human health exposure. One of the options is to use MCCPs in oil-based metal working fluids in enclosed systems (where MCCPs are used continuously). The implications of this option for the environment therefore need to be considered.

B.9.4.1.2 Implications for emission scenarios

The amount of MCCPs assumed to be used in metal working fluids in the EU risk assessment (EC, 2005) was around 5,953 tonnes/year based on figures for 1997 (figures for the EU 15). The available figures for 1994 to 1996 were lower than this level (2,611-5,953 tonnes/year) and showed an increasing trend. The more recently reported consumption in metal working fluids of ~8,920 tonnes/year in 2006 for the EU 25 is higher than the figures for the 1990s (around a 50 % increase since 1997), although the geographical scope has been widened. A similar increase of approximately 35 % compared with 1997 was also evident in 2002 and 2003 (data considered in EC (2005)). Overall it can be concluded that the amounts of MCCPs used in metal working fluids in 2006 are higher than in the 1990s. This possibly reflects the fact that restrictions are now in place on the use of the short-chain chlorinated paraffins in this application (MCCPs are a substitute for this substance).

The main implications of the increased consumption for the emission scenarios would appear to be that the predicted regional and continental releases for use of MCCPs in metal working fluids would increase proportionally to the increase in tonnage (for example the regional release would increase from 1,488 kg/year in 1997 to 2,230 kg/year in 2006). The increase in tonnage would have little or no effect on the predicted local emissions for sites using metal cutting fluids as these are based on a typical amount of metal working fluid that may be used at a site and are not directly related to the overall tonnage used in the EU. The higher consumption figure for 2006 would, however, lead to an increase in the predicted local emission from a metal working fluid *formulation* site compared with that in EC (2005). Using the same methodology as in EC (2005) the local release from formulation of metal working fluids would increase from a figure of 0.83 kg/day to waste water to a figure of 1.2 kg/day to waste water. As the 2005 figure already leads to the identification of potential risks to surface water, sediment and secondary poisoning (earthworm food chain), the higher emission figure based on the 2006 data would lead to identical conclusions. It should also be noted that an evaluation has already been carried out in EC (2005) taking into account that the consumption of MCCPs in metal working fluids could increase as a result of the controls on the use of SCCPs. In Appendix E of EC (2005) it was assumed that the MCCPs usage in this application could increase to around 12,000 tonnes/year and the conclusions obtained using this increased tonnage were broadly the same to those based on the 1997 tonnage.

In relation to the intermittent release scenario for water-based metal working fluids Directive 75/439/EEC appears to be relevant. This scenario effectively assumes that at some sites the fluid present in the whole system (up to 10,000 litres of fluid containing 25 kg of MCCPs) will be replaced at the end of its useful life and that this will be disposed of directly to the sewage treatment plant without any pre-treatment (EC, 2005). However, Directive 75/439/EEC suggests that such discharges should not be allowed. The Directive covers the disposal of "waste oils", which is taken to mean '*any semi-liquid or liquid used product totally or partially consisting of mineral or synthetic oil, including the oily residues from tanks, oil-water mixtures and emulsions'*. As the water-based cutting fluid is an emulsion containing either mineral or synthetic oil (they are made by adding the oil component (typically containing 5 % MCCPs) to water at a dilution of approximately 1:20; thus 10,000 litres of fluid will contain 500 litres of oil and 25 kg of MCCPs – so, the fluid in use will be approximately 5 % by volume oil). Thus it would appear that the requirements of Directive 75/439/EEC would be applicable to water-based cutting fluids. Article 4 of Directive 75/439/EEC states that '*Member States shall take the necessary measures to ensure the prohibition of:*

1. *any discharge of waste oils into internal surface waters, ground water, coastal waters and drainage systems;*
2. *any deposits and/or discharge of waste oils harmful to the soil and any uncontrolled discharge of residues resulting from the processing of waste oils;*
3. *any processing of waste oils causing air pollution which exceeds the level prescribed by existing provisions'.*

However, Article 6 states that '*In order to comply with the measures taken pursuant to Article 4, any undertaking which disposes of waste oils must obtain a permit. This permit shall be granted by the competent authorities after examination of the installations, if necessary. These authorities shall impose the conditions required by the state of technical development*'. Therefore, as discussed in Defra (2008), it appears that it is still possible to dispose of water-based metal cutting fluids directly to surface water provided a permit (presumably a discharge consent) has been granted. Thus, although Directive 75/439/EEC does provide the necessary mechanism by which to prevent the intermittent disposal/releases of water-based metal cutting fluids, it also appears to provide a means by which they can still occur legally provided a permit has been issued. Therefore, full implementation of Directive 75/439/EEC alone may not be sufficient to totally rule out that such intermittent releases could still occur in the future. Defra (2008) indicates that it is the Commission's intention that Directive 75/439/EEC will be repealed and replaced by a new provision in the Waste Framework Directive but it is not yet clear how this would work.

The human health assessment is considering a step-wise approach to reducing inhalation and dermal exposure. One of the options that industry should consider to reduce exposure is for sites using MCCPs in OBMWF to use enclosed machines. According to OECD (2004a) the releases to the environment from sites using such equipment are considered to be negligible. However it would be expected that the losses from the equipment would be collected and sent to external treatment sites for disposal. Therefore the potential for risks to the environment from the use of such enclosed machinery with collection of the oil will shift from the sites of use to the waste disposal or waste management sites.

Information on the waste treatment industry in the EU is given in EC (2006). There are around 14,000 waste treatment installations in the EU. Of these, around 2,900 are waste transfer facilities (of which ~690 deal with hazardous waste), 9,900 are physico-chemical treatment facilities (of which around 620 deal with hazardous waste), 274 are facilities preparing or using waste oil as fuel and 35 are facilities that re-refine waste oil.

The emissions from many waste treatment facilities are controlled under the IPPC regime (for example, installations for the disposal of waste oils as defined in Council Directive 75/439/EEC of 16 June 1975 with a capacity exceeding 10 tonnes per day are covered under IPPC).

Based on the information in EC (2006), there appear to be several stages during the waste treatment process where emissions to the environment could occur, and these are considered below.

- The waste oil is likely to go first to a waste transfer installation. These can either be a stand-alone operation or integrated within a site where subsequent treatment of the waste is carried out (EC, 2006). The main operations carried out at the waste transfer station include bulking and sorting of the waste prior to transfer to the disposal or recovery operation (either on-site or off-site). This can include inspection, sampling, physical sorting and packaging, decanting and blending of the waste. Blending and mixing are carried out at most waste transfer facilities to provide a homogenous and stable feedstock with properties within the required range for the subsequent treatment that is to be used. According to EC (2006), the blending and mixing of waste at such facilities is controlled under the Hazardous Waste Directive 91/689/EEC and can only be carried out if it will not result in risks to humans and the environment.

- Physico-chemical waste treatment facilities carry out a number of processes to treat a range of waste types including oils and oil-water emulsions/cooling lubricants. One of the purposes of the treatment is to separate the oil or the organic fraction from the waste so it can subsequently be used as a fuel. Typical processes that are used to treat oil-water emulsions include sieving and acid splitting (breaking of the emulsion), but could also include organic splitting, oxidation/reduction, flocculation/precipitation, sedimentation, draining and filtration (EC, 2006). Different combinations of the above may be needed to treat different wastes. The output from the process would be, for example, waste water and an oil/organic phase that can subsequently be used as a source of fuel.

- There are two main processes for the recovery of waste oil. One is re-refining of the oil to produce base oils that can be re-used as lubricating oils (around 50-60 % of the initial oil can be recovered). The second is the use of the oil as a fuel (e.g. direct burning in cement factories). EC (2006) indicates that in 1993 around 32 % of the used oils collected in the EU were disposed of by direct burning, 32 % were by re-refining to base oils, 25 % were reprocessed to industrial fuel and 11 % were reclaimed as specific industrial oils. However, EC (2006) suggests that these figures will have now changed significantly (figures for 1999 show that 47 % were incinerated with energy recovery, 24 % were recycled, with a very small amount (~1 %) disposed of and the remainder unaccounted for).

- Many different processes exist (or are in development) for the re-refining of waste oils but not all processes are carried out at every facility. Examples of processes that may be carried out include pre-treatment, cleaning, fractionation and finishing (EC, 2006). Pre-treatment is carried out to remove water and sediments (usually by settling, sedimentation, filtering and centrifuging). In some cases 'light ends' and fuel traces such as naphtha can also be removed. Cleaning includes the removal of asphaltic residues, heavy metals, polymers, additives, degradation compounds, etc., and is usually carried out by acid cleaning (contact with sulphuric acid), although contact with clay can also be used. Once cleaned the waste oil is vacuum distilled and fractionated into the relevant distillation fractions (two to three fractions). Finishing is the final cleaning of the distillation fractions to meet specific product specifications (by improving colour, smell, thermal and oxidation stability, viscosity, etc.). A number of finishing treatments can be used including alkali treatment, bleaching earth, clay polishing, hydrotreatment (used to remove chlorine compounds) and solvent cleaning.

- The amount of re-refined base oil produced in 2000 was around 220,000 tonnes/year[2] and the current EU capacity is estimated at just over 500,000 tonnes/year. The usage of individual installations varies between 35,000 tonnes/year and 160,000 tonnes/year (EC (2006).

- EC (2006) estimates that around 50 % of waste oils are converted into fuel. This includes wastes that cannot be easily re-refined and includes waste oil from ship and tank cleaning, waste oil from oil/water separators, waste oil-water emulsions etc.). It is estimated that around 400,000 tonnes/year of waste oil are burned in cement kilns (representing around 17 % of the total waste oil generated in the EU and 35 % of the waste oil burned[3]). Other uses of waste oil-derived fuels include blast furnaces, other types of kilns (brick, ceramic, lime) large combustion plants, cracking plants, waste incinerators, space heaters and asphalt plants (EC, 2006).

[2] As only 50-60 % of the original oil can be reclaimed from the process, the amount of waste oil used to generate this volume would be of the order of 370,000-440,000 tonnes/year.

[3] Based on these figures, the total amount of waste oil generated in the EU would be around 2,400,000 tonnes/year.

- Some waste oil is burned directly without any pre-treatment. However, to allow the waste oil to be used in a wider range of combustion sources, various reprocessing methods can be used including removal of water and sediment, removal of metals, thermal cracking, hydrogenation or gasification. In some cases fuels can be obtained by blending different types of hazardous waste (for example blending liquid and semi-liquid waste with a high organic content including waste solvents, oils, oil sludges, emulsions, distillation residues and tank bottom sludges). In addition, stable emulsion fuels with high organic carbon contents can also be blended from hazardous wastes (EC, 2006).

There are a number of factors that make it difficult to generate a generic emission scenario for waste oil treatment. For example, waste composition is very variable, and a large number of contaminants other than MCCPs may be present. As a result, no two waste treatment facilities will be the same with each accepting a different range of wastes based on the local situation (EC, 2006). However, EC (2006) does give examples of the concentration (or amount) of oil that may be present in the waste water stream from such facilities and one way to estimate the amounts of MCCPs that may be released from such facilities would be to assume that they behave in a similar way to the oil during the various treatment methods. Thus it may be possible to estimate the amount of MCCPs that may be present in these streams by scaling the oil concentrations based on the relative amounts of oil and MCCPs that would be in the waste taken by the plant. This is outlined below.

- The amount of MCCPs currently used in metal working fluids (both oil-based and water-based) is around 8,920 tonnes/year (2006 data). Assuming an MCCPs content in the oil of 5-10 %, the total amount of lubricant oil (neat oil and oil in emulsions) containing MCCPs produced in the EU would be around 89,200 to 178,400 tonnes/year. As indicated above, the total amount of waste oil currently treated in the EU is around 2,400,000 tonnes/year. If all of the oil (and emulsions) containing MCCPs were collected and sent to waste treatment this would account for around 3.7-7.4 % of the oil recovered. Thus, around 3.7-7.4 % of the concentration (or amount) of oil present in the waste water from the waste treatment facilities would arise from the use of MCCPs, and the MCCPs content would be only 5-10 % of this concentration (or amount).

  For waste transfer stations, EC (2006) gives an example figure for the emission of oil to sewer as 150 kg/year. Using the scaling approach as outlined above, the MCCPs content of this oil would be estimated as around 0.56 kg/year, or 0.0019 kg/day assuming 300 days of operation.

  The example waste transfer station given in EC (2006) handled around 380 tonnes/year of waste. Thus the emission factor for oil from the site is around 0.39 kg oil per tonne waste. Assuming that the same emission factor holds for the components of the oil (i.e. that an emission factor of 0.39 kg MCCPs per tonne of MCCPs waste is appropriate[4]), and is applicable to other waste transfer operations in the EU (i.e. the composition of waste in the example is representative of the situation in

[4] This is only an approximation as not all waste treated at the waste transfer station will be waste oil.

the EU as a whole), the total MCCPs emission from this source can be estimated as 3,480 kg/year assuming that all of the MCCPs tonnage (8,920 tonnes/year) is handled at such facilities. Another estimate for the total EU emission from this source can be obtained based on the MCCPs emission per site being 0.56 kg/year (see above) and assuming that there are 2,900 waste transfer sites in the EU emitting at this rate. This would give an EU-wide emission of around 1,624 kg/year, which is of a similar order to the figure above.

- For a physico-chemical treatment facility, EC (2006) gives a figure of 30-90 kg of oil generated waste per tonne of total waste processed. The oil is generally recycled. The concentration of oil in the waste water from such plants is typically in the range 5-10 mg/l and 836 kg of waste water is generated per tonne of waste treated (EC, 2006). Scaling the oil concentration in the waste water (using the mid-point of the concentration range of 7.5 mg/l) to the amount of MCCPs that may be present (3.7% × 10%) would lead to an estimated MCCPs concentration in the waste water of around 0.028 mg/l. This concentration will be used as the basis of the PEC calculation for this type of facility.

  The total waste capacity of the physico-chemical treatment facility sites on which these data are based is 850,000 tonnes/year. Assuming the amount of waste water generated is 836 kg/tonne of waste treated, the total amount of MCCPs emitted from these sites would be around 20 kg/year using the estimated waste water concentration above.

- EC (2006) indicates that there are no comprehensive data available on the composition of the waste oils received by facilities specialising in the recovery of waste oils. Several sources of chlorine in the used oil exist including lubricating oil additives, cold-flow additives and contamination with chlorinated solvents and transformer oils. EC (2006) considers the distribution of various components of the waste oil between emissions to air and sewer and incorporation into the final product. This analysis did not consider MCCPs but, based on the other substances considered, it would be expected that the majority of the MCCPs present in the waste oil would remain in the re-refined oil products. EC (2006) indicates, however, that if a hydrotreater is incorporated into the re-refining process then this will destroy any chlorinated organic compounds present in the oil.

  The concentration range of hydrocarbons in the effluent from waste oil re-refining facilities is given as 5-15 mg/l (EC, 2006). Using a similar approach to that described above, the equivalent concentration of MCCPs in the waste water stream can be estimated as 0.037 mg/l (using the mid-point of the concentration range for oil in the waste water of 10 mg/l and a scaling factor of 3.7% × 10%). This concentration will be used as the basis for the PEC calculation for this type of facility.

  The amount of waste water generated at four example facilities is given as 0.12 m^3/tonne waste oil at a facility treating 15,000 tonnes/year, 0.31 m^3/tonne waste oil at a facility treating 19,960 tonnes/year, 4.14 m^3/tonne waste oil at a facility treating 90,500 tonnes/year and 6.46 m^3/tonne waste oil at a facility treating 46,208 tonnes/year. Assuming that the concentration of waste oil in the effluent stream is in the range 5-15 mg/l as above, then the mass emission factor for the oil from these four plants can be estimated to be roughly between 6×10^{-5} % of the oil treated to 9.9×10^{-3} % of the oil treated. Assuming these emission factors are also applicable to the amount of MCCPs present in the waste oil (assumed to be a maximum of 8,917 tonnes/year in 2006), the total EU emission from this source would be in the range 5 to 864 kg/year.

EC (2006) gives a similar figure of 2-10 mg/l for the concentration of waste oil in the effluent stream of facilities that prepare hazardous waste for subsequent use as a fuel.

As well as waste water, these processes are also likely to generate oil-contaminated sludges. These are either incinerated or disposed of appropriately as solid waste.

In summary, the following emissions will be assumed for waste treatment operations in this report:

Waste transfer facility	Local	0.56 kg/year or 0.0019 kg/day over 300 days to waste water
	Total EU	1,624-3,480 kg/year to waste water
	Regional	162-348 kg/year to waste water
Physico-chemical treatment facility	Local	Concentration in waste water 0.028 mg/l
	Total EU	20 kg/year to waste water
	Regional	2 kg/year to waste water
Oil re-refining facility	Local	Concentration in waste water 0.037 mg/l
	Total EU	up to 864 kg/year to waste water
	Regional	up to 86.4 kg/year to waste water

The above emission estimates on the EU and regional scales should be considered as worst case estimates as the total EU emission is estimated each time based on the total amount of MCCPs used in metal cutting fluids. In practice, this amount will be split between the various treatment processes (and some will be destroyed by incineration) and so the actual emission from any one process is likely to be lower than estimated here.

For the physico-chemical treatment facility and the oil re-refining facility, the local PECs are estimated based on a concentration in waste water. It is likely that this waste water stream will be diluted with waste water from other sources at the waste water treatment facility and so the actual concentration of MCCPs entering the waste water treatment plant will be lower than estimated here. In order to take this into account, a dilution by a factor of 2 is considered in the calculation (assuming 300 days of operation, the amount of waste water generated at the above four example oil re-refining sites can be estimated to be 6, 21, 1,249 and 995 m^3/day, which are between a factor of 1.6 and 333 times lower than the flow of the standard (default) waste water treatment plant (2,000 m^3/day)).

B.9.4.2 Use of MCCPs in PVC

B.9.4.2.1 New information obtained during consultation on the draft risk reduction strategy

Euro Chlor (2008b) indicates that 63,691 tonnes of MCCPs were sold in the EU 25 in 2006. Of this, 49 % (~31,200 tonnes) were thought to be used in PVC. It is possible that other EU suppliers exist who are not members of Euro Chlor, in which case these figures might be underestimates of the total EU supply to some extent.

A total of 6,681 tonnes of MCCPs were sold in Germany and Austria combined in 2006 with around 17 % of this (~1,140 tonnes) being used in PVC (Euro Chlor, 2008b).

KEMI (2008) reports that around 3.5 tonnes/year of MCCPs were used in Sweden in 2005 for the production of plastics. It is not clear whether this figure is for PVC or other types of plastics.

SFT (2008) report no use of MCCPs by Norwegian producers of PVC in 2005 but indicate that import of MCCPs in PVC articles could occur.

Euro Chlor (2008a) indicate that MCCPs are used in a wide range of flexible PVC applications including, notably, those applications where fire resistance is essential (e.g. cables and safety flooring). MCCPs are compatible with a range of plasticisers and, according to Euro Chlor (2008a) do not impede the recycling of flexible PVC. This latter point is relevant as the Vinyl 2010 initiative[5] has set a post-consumer recycling target for 2010 of 200,000 tonnes of PVC. The amounts of PVC recycled under this initiative are 83,000 tonnes in 2006 and 149,500 tonnes in 2007.

Euro Chlor (2008a) states that **ALL** PVC converters using MCCPs apply best practice with exhaust recovery and incineration (Euro Chlor does not know of any exceptions).

B.9.4.2.2 Implications for emission scenarios

The amount of MCCPs assumed to be used in PVC in the EU risk assessment (EC, 2005) was around 51,827 tonnes/year based on figures for 1997 (figures for the EU 15). The available figures for 1994 to 1996 were similar to this level (45,476-49,240 tonnes/year). The more recently reported consumption in PVC of ~31,200 tonnes/year in 2006 for the EU 25 is considerably lower than the

[5] http://www.vinyl2010.org/Home/Home/Our_Voluntary_Commitment/

figures for the 1990s (around a 40 % reduction since 1997). A similar reduction of around 35-40 % was also evident in 2002 and 2003 compared with 1997 (data considered in EC (2005)) indicating that the amount of MCCPs used in PVC has been reasonably stable at around 31,000 tonnes over the period 2002 to 2006.

Although the new data suggest that the amount of MCCPs used in PVC has declined since 1997 (the base year for the original EU risk assessment (EC, 2005)), this actually has little impact on the local emission estimates. This is because the amount of MCCPs assumed to be used on a site in EC (2005) is based on the amount of PVC known to be processed at representative sites (taken from OECD (2004b)), rather than the total MCCP tonnage used in the EU. The amounts of PVC, and hence MCCPs, used at a local site are summarised in Table 9.3 (data taken from EC (2005)). It will be assumed that these data are also relevant for this current analysis. The rationale for this is that the reduction in consumption of MCCPs in PVC is most likely to occur through a reduction in the number of sites where MCCPs are used rather than a general decrease in the use of MCCPs across all sites.

Table 9.3 Estimated amounts of MCCPs used at flexible PVC processing sites

Type of processing	Amount of PVC processed (tonnes/year)	Amount of MCCPs used per site (tonnes/year)	
		10% MCCPs in resins (coating process)	15% MCCPs in resins (extrusion/other process)
Open system	744	74.4	112
Partially open system	3,990	-	599
Closed system	341	-	51

In contrast to the local emissions, the reduction in use of MCCPs in PVC will have a marked impact on the regional and continental emissions from this source.

The other main implication of the new data for the emission scenarios in EC (2005) is that it has now been confirmed that all PVC converters using MCCPs apply best practice with exhaust recovery and incineration. The approach used in EC (2005) – which was based on the OECD Emission Scenario Document for plastics additives (OECD, 2004b) – assumed that such equipment would be present only at the largest sites.

The emission factors assumed in EC (2005) for conversion are summarised in Table 9.4.

Table 9.4 Summary of emission factors from PVC conversion assumed in the original risk assessment report

Process	Type of system	Emission factor[1]		Amount of MCCPs used/site (tonnes/year)	Release of MCCPs/site (kg/year)[1]	
		Air emission control	No air emission control		Air emission control	No air emission control
Calendering	Open	0.15% [0.07%]	1.5% [0.7%]	112	168 [78]	
Extrusion	Partially open	0.03% [0.014%]	0.3% [0.14%]	559	180 [84]	
	Closed	0.03% [0.014%]	0.3% [0.14%]	51		153 [71]
Injection moulding	Closed	0.03% [0.014%]	0.3% [0.14%]	51		153 [71]
Plastisol spread-coating	Closed	0.15% [0.07%]	1.5% [0.7%]	74.4	112 [52]	

Notes: 1 - The emission factors and estimates given are for an MCCPs product with a 45% chlorine content. The equivalent factors for an MCCPs product with a 52% chlorine content are shown in square brackets. See EC (2005) for a discussion of the relative volatility of the 45% and 52% chlorine content products.

As discussed in EC (2005) and evident from Table 9.4, air emission control was assumed to be in place at conversion sites for the local calculations for calendering, extrusion (partially open systems), and plastisol spread-coating. However, no air emission control was assumed to be in place at conversion sites for the local calculations for extrusion (closed systems) and injection moulding (here OECD (2004b) indicates that the emission factor could be a factor of 10 higher than at sites with emission controls). The new information therefore suggests that the emissions from conversion should be around ten times lower than assumed in EC (2005) for these two scenarios. The revised emission estimates from **conversion** are therefore as follows:

For the 45% wt. Cl MCCPs (assumed to be released to waste water)

Calendering - open 168 kg/year (0.56 kg/day)

Extrusion – partly open 180 kg/year (0.60 kg/day)

Extrusion – closed 15.3 kg/year (0.051 kg/day)

Injection moulding – closed 15.3 kg/year (0.051 kg/day)

Plastisol spread-coating 112 kg/year (0.37 kg/day)

For the 52% wt. Cl MCCPs (assumed to be released to waste water)

Calendering - open 78 kg/year (0.26 kg/day)

Extrusion – partly open 84 kg/year (0.28 kg/day)

Extrusion – closed 7.1 kg/year (0.024 kg/day)

Injection moulding – closed 7.1 kg/year (0.024 kg/day)

Plastisol spread-coating 52 kg/year (0.17 kg/day)

These revised estimates are all based on the emission factors from OECD (2004b) for sites with emission controls. These emissions will be initially to air as hot gases. OECD (2004b) recommends that, in the absence of information, it should be assumed that 50 % of these emissions will be released to air and 50 % will eventually be released to waste water (through condensation and subsequent washing/cleaning of equipment, etc.). This assumption was used in the PEC calculations in EC (2005) and the same assumptions will be used here.

It should be noted that in EC (2005) emissions of MCCPs from the compounding stage of PVC processing were also estimated. Here it was assumed that a worst case loss of 0.01 % to waste water occurred during raw materials handling (through spillage, etc.) and that a volatile loss to air of 0.03 % (for a 45 % wt. Cl MCCPs) or 0.014 % (for a 52 % wt. Cl MCCPs) occurred during dry blending of the MCCPs into the PVC prior to conversion. The release to air from plastisol blending for coating processes was assumed to be negligible. These factors were based on the approach given in OECD (2004b) taking into account the relative volatility of the two MCCPs considered. Again as the volatile losses occurred at elevated temperature, it was assumed that 50 % of the release would be eventually to air and 50 % would be eventually to waste water.

From the new information provided, it is unclear whether exhaust recovery and incineration are also applied during the dry blending (compounding process). If such methods are used then the emission factor from this process would be expected to be lower (for example by a factor of 10) than assumed in EC (2005). No information was provided on the potential for emission to waste water from spillage, etc., so it is not currently possible to refine these estimates. The revised emission estimates (based on the approach in EC (2005)) for the **compounding** step are summarised below:

Raw materials handling - for both 45% wt. Cl and 52% wt. Cl MCCPs (assumed to be released to waste water)

Open processing	coating	7.4 kg/year (0.025 kg/day)
Open processing	extrusion/other	11.2 kg/year (0.037 kg/day)
Partially open processing	extrusion/other	59.9 kg/year (0.20 kg/day)
Closed processing	extrusion/other	5.1 kg/year (0.017 kg/day)

Dry blending – for 45% wt. Cl MCCPs (assumed to be released 50% to air and 50% to waste water)

		Assuming no emission control	**Assuming emission control**
Open processing	extrusion/other	33.6 kg/year (0.11 kg/day)	3.4 kg/year (0.011 kg/day)
Partially open processing	extrusion/other	180 kg/year (0.60 kg/day)	18 kg/year 0.060 kg/day)
Closed processing	extrusion/other	15.3 kg/year (0.051 kg/day)	1.5 kg kg/year (0.0051 kg/day)

Dry blending – for 52% wt. Cl MCCPs (assumed to be released 50% to air and 50% to waste water)

		Assuming no emission control	**Assuming emission control**
Open processing	extrusion/other	15.7 kg/year (0.052 kg/day)	1.6 kg/year (0.0052 kg/day)
Partially open processing	extrusion/other	83.9 kg/year (0.28 kg/day)	8.4 kg/year 0.028 kg/day)
Closed processing	extrusion/other	7.1 kg/year (0.023 kg/day)	0.71 kg kg/year (0.0023 kg/day)

Plastisol blending for coating processes

Assumed to be negligible

For the regional emissions from conversion, no emission control was assumed to be present at conversion sites as a worst case. The new information suggests that emission control can now be assumed to be in place at all conversion sites, and so the emission factors used for the regional emission calculation for conversion sites should be ten times lower than assumed in EC (2005).

In EC (2005), the regional emissions from PVC compounding and conversion were estimated assuming that 25 % of the PVC containing MCCPs was processed in closed systems, 49 % in partially open systems and 26 % in open systems. In addition it was considered that the 52 % wt. Cl products made up around two thirds of the total MCCPs used in this application and that around 70% of the MCCPs were compounded in dry blending processes. The regional emissions estimated in EU (2005) from PVC compounding and conversion were 869 kg/year to waste water and 351 kg/year to air from the compounding stage and 10,215 kg/year to waste water and 10,215 kg/year to air from conversion, based on the tonnage used in this application in 1997.

The revised estimates, based on the known tonnage of MCCPs that are used in PVC in 2006 (~31,200 tonnes/year) and assuming that emission controls are in place at all conversion sites are shown below (using the same assumptions as in EC (2005) for the relative use of 52% wt. Cl MCCPs compared to 45% wt. Cl MCCPs and the fractions used in open, partially open and closed systems). As the situation with regards to the use of emission controls during the dry blending (compounding) process is unclear, the regional emissions have been estimated assuming both that a) air emission controls are present and b) that air emission controls are not present during compounding, to indicate the possible range.

Compounding – assuming air emission controls are present

	Regional	**Total EU**
Raw materials handling	312 kg/year to waste water	3,120 kg/year to waste water
Dry blending	21.1 kg/year to waste water	211 kg/year to waste water
	21.1 kg/year to air	211 kg/year to air
Total	333 kg/year to waste water	3,331 kg/year to waste water
	21.1 kg/year to air	211 kg/year to air

Conversion– assuming air emission controls are present[6]

Regional	**Total EU**
615 kg/year to waste water	6,153 kg/year to waste water

[6] The assumed emission factors are 0.15% for open and 0.03% for partially open and closed systems for 45% wt. Cl MCCPs and 0.07% for open and 0.014% for partially open and closed systems for 52% wt. Cl MCCPs.

615 kg/year to air	6,153 kg/year to air

EC (2003) considers a number of methods for treating waste gases generated in industrial processes, including thermal oxidation and catalytic oxidation.

Thermal oxidisers are used to control volatile organic carbon (VOC) emissions from a number of industrial processes, including rubber products and polymer manufacturing and flexible vinyl and urethane coating processes (EC, 2003). Typical temperatures of operation range between 750 to 1,000°C, with higher temperatures (980 to 1,200°C) being used if hazardous components are present (EC, 2003).

The typical VOC removal rate for such methods are between 98 and >99.9 % for straight thermal oxidisers, between 95 and 99 % for regenerative thermal oxidisers and between 98 and 100 % for recuperative thermal oxidisers[7] (EC, 2003). The typical removal rates for particulate matter (PM_{10}) are between 50 and 99.9 % for a straight thermal oxidiser, and 50 to 99.9 % for a recuperative thermal oxidiser (no figures were given for a regenerative thermal oxidiser) (EC, 2003). EC (2003) also indicates that if sulphur or halogens are present in the gas stream (as is very likely to be the case in relation to PVC), then further flue gas treatment may be needed. This could include water or alkaline scrubbing to absorb hydrogen chlorides or activated carbon adsorption if chlorinated dioxin formation is not prevented during the incineration stage.

Catalytic oxidisers are similar to thermal oxidisers except that the exhaust gases from the combustion chamber pass through a catalyst prior to release (EC, 2003). The waste gases entering the catalytic oxidiser are heated to around 300-500°C before entering the catalyst bed (the maximum temperature of the catalyst is 500-700°C). The catalysts used are usually either precious metals (e.g. palladium, platinum or rhodium) or base metals or single or mixed metal oxides (e.g. oxides of copper, chromium, manganese, nickel, cobalt). The metal is usually supported on a carrier (metal or ceramic). For chlorinated compounds, catalysts such as chromia/alumina, cobalt oxide and copper oxide/manganese oxide tend to be used (EC, 2003). The catalysts have a working life of around two years or more after which they are either regenerated or disposed of. Examples of industry sectors where catalytic oxidisers are used include rubber products and polymer manufacturing (EC, 2003).

The typical removal rates for catalytic oxidisers for VOCs are 95 to 99 % for straight catalytic oxidisers and 90 to 99 % for regenerative catalytic oxidisers. The typical removal rates for particulate matter (PM_{10}) are between 50 and 99.9 % for a straight catalytic oxidiser (no figures were given for a regenerative thermal oxidiser) (EC, 2003). Again where halogens are present in the gas stream, EC (2003) indicates that further flue gas treatment may be needed in order to minimise the emission of hydrogen halides.

[7] A straight thermal oxidiser consists of a combustion chamber and no heat recovery of exhaust air is carried out. In regenerative and recuperative thermal oxidisers the thermal energy of the exhaust air is reclaimed and used to pre-heat the incoming gases prior to combustion.

B.9.4.3 Revised PECs for metal working and PVC

B.9.4.3.1 Regional PECs

The PECs for the new scenarios for the recycling/recovery of waste metal working fluids and the various PVC scenarios given in EC (2005) have been (re)calculated based on the changes to the emission estimates discussed in the previous Sections. In order to take account of the fact that the amounts of MCCPs used in the various applications in the EU may have changed since the PECs in EC (2005) were calculated, the regional emissions from EC (2005) have been "scaled" to the amounts of MCCPs thought to be used in the EU in 2006[8].

The 2006 use pattern for MCCPs was outlined in Euro Chlor (2008b). This gave a total of 63,691 tonnes sold in the EU 25 with 49 % used in PVC, 14 % used in metal working, 16 % used in sealants and adhesives, 10 % used as a flame retardant in rubber and textiles, 1 % used in leather fat liquors with the remaining 9 % for other/unknown uses. A comparison between the 1997 and 2006 use pattern is given in Table 9.5.

Table 9.5 Comparison of use patterns between 1997 and 2006

Use	**Quantity (tonnes/year)[1]**	
	1997	**2006**
PVC	51,287 [79.4%]	31,209 [49%]
Metal working/cutting fluids	5,953 [9.1%]	8,917 [14%]
Paints, adhesives and sealants	3,541 [5.4%]	10,191 [16%]
Rubber/polymers (other than PVC)	2,146 [3.3%]	6,369 [10%]
Leather fat liquoring	1,048 [1.6%]	637 [1%]
Carbonless copy paper	741 [1.1%]	
Other/unknown		5,732 [9%]
Total	65,256	63,691

Notes: 1 - Values in square brackets represent the percentage of the total use.

The extrapolated ("scaled") regional and total EU emissions for 2006 are summarised in Table 9.6.

[8] Since the regional (and total EU) emissions in 2006 are broadly directly proportional to the tonnage used in each application it is possible to scale the regional emission simply by considering the changes that have occurred in the tonnage for each application as a first approximation.

Table 9.6 Extrapolated regional and total EU emissions for 2006

Scenario	Emissions reported in EU (2005) – 1997 data (kg/year)		Extrapolated emissions for 2006 (kg/year)	
	Regional	Total EU	Regional	Total EU
Production	65 to waste water	65 to waste water 37 to surface water	65 to waste water	65 to waste water 37 to surface water
PVC - compounding	869 to waste water 351 to air	8,686 to waste water 3,506 to air	333-523 to waste water[5] 21.1-211 to air[5]	3,331 to waste water[5] 211-2,110 to air[5]
PVC - conversion	10,215 to waste water 10,215 to air	102,150 to waste water 102,150 to air	615 to waste water[5] 615 to air[5]	6,153 to waste water[5] 6,153 to air[5]
Use in rubber/plastics - compounding	32.3 to waste water 10.8 to air	323 to waste water 108 to air	96 to waste water 32 to air	959 to waste water 319 to air
Use in rubber	108 to waste water 108 to air	1,074 to waste water 1,074 to air	321 to waste water 321 to air	3,187 to waste water 3,187 to air
Sealants and adhesives[2]	negligible	negligible	negligible	negligible
Paints and varnishes[2] - formulation	354 to waste water 118 to air	3,540 to waste water 1,180 to air	1,019 to waste water 340 to air	10,191 to waste water 3,397 to air
Paints and varnishes[2] – industrial application of paints	118 to waste water	1,180 to waste water	340 to waste water	3,397 to waste water
Metal cutting/working fluids - formulation	1,488 to waste water	15,363 to waste water	[2,229 to waste water][6]	[23,012 to waste water][6]
Metal cutting/working fluids – use in oil-based fluids	38,100 to waste water	381,000 to waste water	[57,070 to waste water][6]	[570,700 to waste water][6]
Metal cutting/working fluids – use in emulsifiable fluids	99,200 to waste water	992,000 to waste water	[148,592 to waste water][6]	[1,485,917 to waste water][6]
Metal cutting/working fluids – recovery/recycling	not included	not included	436 to waste water[5]	4,364 to waste water[5]
Leather fat liquors - formulation	315 to waste water 105 to air	3,150 to waste water 1,050 to air	191 to waste water 64 to air	1,911 to waste water 637 to air

Scenario	Emissions reported in EU (2005) – 1997 data (kg/year)		Extrapolated emissions for 2006 (kg/year)	
	Regional	Total EU	Regional	Total EU
Leather fat liquors - processing	1,050 to waste water	10,500 to waste water	638 to waste water	6,370 to waste water
Carbonless copy paper - recycling	3,705 to waste water	37,050 to waste water	0 to waste water	0 to waste water
Service life - PVC	2,590 to waste water 2,590 to air	25,900 to waste water 25,900 to air	1,560 to waste water 1,560 to air	15,596 to waste water 15,596 to air1
Service life – rubber/polymers	107 to air	1,070 to air	318 to air	3,176 to air
Service life – paints[2]	1,240 to waste water 3,300 to air	12,400 to waste water 33,000 to air	3,570 to waste water 9,500 to air	35,697 to waste water 95,000 to air
Service life - adhesives and sealants[2]	10,600 to waste water 118 to air	106,000 to waste water 1,180 to air	30,515 to waste water 340 to air	305,154 to waste water 3,397 to air
Waste remaining in the environment - PVC	16,600 to waste water 22,050 to surface water 90 to air 66,200 to urban/industrial soil	166,000 to waste water 220,500 to surface water 900 to air 662,000 to urban/industrial soil	9,996 to waste water 13,278 to surface water 54 to air 39,864 to urban/industrial soil	99,961 to waste water 132,780 to surface water 542 to air 398,641 to urban/industrial soil
Waste remaining in the environment – rubber/polymers	2,120 to surface water 8 to air 6,360 to urban/industrial soil	21,200 to surface water 80 to air 63,600 to urban/industrial soil	6,292 to surface water 24 to air 18,876 to urban/industrial soil	62,918 to surface water 237 to air 188,755 to urban/industrial soil
Waste remaining in the environment – paints[2]	2,730 to surface water 11 to air 5,650 to urban/industrial soil	27,300 to surface water 110 to air 56,500 to urban/industrial soil	7,859 to surface water 32 to air 16,265 to urban/industrial soil	78,592 to surface water 317 to air 162,653 to urban/industrial soil
Waste remaining in the environment – sealants and adhesives[2]	5,470 to surface water 22 to air 16,480 to urban/industrial soil	54,700 to surface water 220 to air 164,800 to urban/industrial soil	15,747 to surface water 63 to air 47,443 to urban/industrial soil	157,471 to surface water 633 to air 474,428 to urban/industrial soil

Scenario	Emissions reported in EU (2005) – 1997 data (kg/year)		Extrapolated emissions for 2006 (kg/year)	
	Regional	Total EU	Regional	Total EU
Total not including waste remaining in the environment[3, 4]	170,049 to water (split 136,039 to waste water and 34,010 to surface water) 17,023 to air	1,700,392 to water (split 1,360,284 to waste water and 340,108 to surface water) 170,216 to air	39,889 to water (split 31,911 to waste water and 7,978 to surface water) 13,299 to air	398,312 to water (split 318,620 to waste water and 79,692 to surface water 132,973 to air
Total including waste remaining in the environment[3, 4]	219,019 to water (split 149,319 to waste water and 69,700 to surface water) 17,154 to air 94,690 to urban/ industrial soil	2,190,092 to water (split 1,493,084 to waste water and 697,008 to surface water) 171,526 to air 946,900 to urban/ industrial soil	92,061 to water (split 39,908 to waste water and 53,153 to surface water) 13,472 to air 122,448 to urban/ industrial soil	930,034 to water (split 398,589 to waste water and 531,445 to surface water) 134,703 to air 1,224,447 to urban/ industrial soil

Notes:
1 - Taken from this report (see Section B.9.5.2.2)
2 - EU (2005) assumes that the usage in paints, sealants and adhesives is split two thirds sealants and adhesives to one third paints. The same assumption has been used here. However it should be noted that the 2006 data are for sealants and adhesives only and it is not clear if this figure also includes paints and other coatings.
3 - The calculations in EU (2005) were carried out both with and without waste remaining in the environment.
4 - In EC (2005) a 70% connection rate to waste water treatment plants was assumed (an earlier version of EUSES was used in the calculation). An 80% connection rate has been assumed here in line with the approach included in EUSES v2.0.3).
5 - Estimated in this report (Section B.9.5.1 □ and Section B.9.5.2).
6 - The risk reduction measures being considered for metal working fluids would lead to a marked reduction in the emissions to the environment from these sources. For this analysis these emissions have not been considered in the total regional and continental emissions.

Based on these calculations, it can be seen that the overall emissions to the environment would be expected to reduce from a total figure of around 3,310,000 kg/year in 1997 to around 2,290,000kg/year mainly as consequence of the risk reduction measures being considered for metal working fluids.

The PECs and risk characterisation ratios calculated using the new emission estimates are summarised below. It should be noted that in EC (2005) the regional concentrations in surface water, sediment and soil were based on measured data. The same measured data are used here for the regional concentrations. The regional concentrations assumed in the assessment, along with those predicted by EUSES 2.0.3 using the emission estimates for 2006 in Table 9.7 are summarised below.

Table 9.7 Regional concentrations

Compartment	Regional concentration		
	Value used in evaluation[1]	Predicted value for 1997 (EC 2005)[2]	Predicted value for 2006[2]
Surface water	0.1 µg/l	0.75 µg/l	0.31 µg/l
Freshwater sediment	0.7 mg/kg wet wt.	16.9 mg/kg wet wt.	8.0 mg/kg wet wt.
Agricultural soil	0.088 mg/kg wet wt.	55.8 mg/kg wet wt.	2.3 mg/kg wet wt.
Industrial/urban soil	0.088 mg/kg wet wt.	173 mg/kg wet wt.	37.5 mg/kg wet wt.
Natural soil	0.088 mg/kg wet wt.	2.0 mg/kg wet wt.	0.65 mg/kg wet wt.
Marine water		Not considered[3]	0.043 µg/l
Marine sediment		Not considered[3]	1.09 mg/kg wet wt.

Notes: 1 - Based on measured data (see EC (2005)).
2 - Predictions include waste remaining in the environment.
3 - No marine risk assessment was carried out in EC (2005).

B.10 Risk characterisation

For the human health risk characterisation, a comparison of the DNELs and the exposure levels should be carried out to yield the Risk Characterisation Ratios (RCR). According to REACH, if, exposure is less than the relevant DNEL (i.e. the risk characterisation ratio (RCR) <1) then the risk is adequately controlled. If exposure is greater than the relevant DNEL (i.e. RCR >1) then the risk is NOT controlled. The RCR for combined exposure is calculated by adding the relevant inhalation and dermal RCRs together and if they are <1 then the risk is adequately controlled.

For the environment risk characterisation, the exposure levels are compared to PNECs rather than DNELs, but the resulting decision-making is the same.

B.10.1 Human health

B.10.1.1 Workers

B.10.1.1.1 Use of oil-based metal working fluids

The RCRs based on RWC exposures for OBMWF with an MCCPs content of 10 (major uses) and 70 % (heavy duty uses) are outlined in Table 10.1.

Table 10.1 Risk characterisation ratios for inhalation, dermal and combined RWC exposures during the use of oil-based metal working fluids

Reasonable worst case exposure scenario	RCR	
	10 % (major uses)	**70 % (heavy duty uses)**
RCR for inhalation	0.3 / 1.6 = 0.19	2.4 / 1.6 = **1.5**
RCR for dermal	51 / 11.5 = **4.4**	357 / 11.5 = **31**
RCR for combined exposure	0.19 + 4.4 = **4.6**	1.5 + 31 = **32.5**

As can be seen from Table 10.1 the highest proportion of the risks associated with MCCPs come from the dermal route. Although, no typical inhalation exposures were derived in the RAR typical dermal exposures were calculated in the RAR. The RCRs for typical dermal exposure are outlined in Table 10.2.

Table 10.2 Risk characterisation ratios for typical dermal exposures during the use of oil-based metal working fluids

Typical exposure scenario	RCR	
	10 % (major uses)	**70 % (heavy duty uses)**
RCR for dermal	7 / 11.5 = 0.6	52 / 11.5 = **4.5**

<u>Conclusion</u>

The RCRs for all RWC and typical exposures, except the RWC inhalation exposure for a 10 % MCCPs product and the typical dermal exposure for a 10 % product, show that the risks are not adequately controlled (RCR >1). If, the combined exposure for an OBMWF with a 10 % MCCPs content had been derived from the typical dermal and RWC inhalation exposure the RCR indicates that the risks are adequately controlled (RCR <1).

As discussed above, typical dermal and RWC inhalation exposures to OBMWFs with 10 % or less MCCPs are adequately controlled. What these results show is that it is possible for adequate control to be achieved for the majority of uses and for the majority of users. Therefore if the principles and hierarchy of control as outlined in the CAD are followed for the vast majority of exposed workers the risk will be adequately reduced. Compliance with the requirements of CAD will help to ensure that exposures are reduced.

However, for OBMWFs with an MCCPs content of greater than 10 % the risks are not adequately controlled (even taking into account typical dermal exposures).

Therefore, there is a need to limit the human health risks (particularly those associated with the dermal route) associated with the use of greater than 10% MCCPs in oil-based metal cutting /working fluids (OBMWFs). Across the EU, companies of all sizes (small, medium and large) are engaged in metalworking, and many may use OBMWFs containing MCCPs. Information on the exact tonnage of MCCPs use in OBMWFs in the EU is not available; however, according to Cefic 8,113 tonnes were employed in formulating metal working/cutting fluids in 2003 (Cefic, 2004).

As, discussed earlier the highest proportion of exposure of MCCPs to workers when using OBMWFs comes from the dermal route. However, it is worth noting that there are uncertainties associated with the dermal exposure data. The dermal exposure to MCCPs in OBMWFs has been estimated from surrogate data in which MWF exposure was sampled using boron as a marker of contamination. Dermal exposure to MWF was calculated based on the mass of boron on wipe samples and the concentration of MCCPs calculated from this. It is therefore, likely that the actual exposure received by the workers to MCCPs could be overestimated.

Despite the uncertainties associated with the dermal exposure data there is a need to reduce the potential risks for workers being exposed to OBMWFs containing MCCPs at >10 %. Therefore, the following stepwise approach should be taken by industry to reduce both dermal and inhalation exposure when MCCPs are used in OBMWFs at >10 %. This approach mirrors what companies **should already** be doing in order to follow the principles of good practice as required by CAD.

1. Where practical MCCPs in OBMWFs should be substituted with an alternative substance of lower hazard and risk. If it is not possible to substitute industry should justify in their risk assessments why the alternatives (some of which are outlined in Section C) are not suitable for the specific process they are carrying out.

2. Where there is continuous use of OBMWFs containing >10 % MCCPs all the following RMMs must be put in place and followed:
    - the process should be enclosed;
    - autofeed of the parts;
    - autocollection of the parts;
    - components should be collected into a container to take to and during cleaning/de-oiling. This reduces exposure to fluids during

transport and cuts from sharps. It can increase productivity by using bulk handling rather than single components to be moved;
- when dealing with concentrates a pump should be used to transfer the substance for dilution. Using a pump will ensure that concentrates are not poured and this will prevent spillage, prevent skin contact with the concentrate and prevent splashing.

3. Where there is frequent use (i.e. some use every day but it is not continuous) of OBMWFs containing >10 % MCCPs the following RMMs should be put in place:
   - a foot operated solenoid should be used to control the flow of MWF, i.e. fluid only flows when the 'cutting' is in progress. Operators should not put their hands near the tool when 'cutting' is in progress. This will prevent hands becoming soaked in wet fluid when dealing with tools and workpieces on the tool. There are cost benefits to doing this; fluid aerosols are not created, wastage of MWFs is reduced, mixing with oxygen is reduced thus giving longer life;
   - splash guard at the machine;
   - components should be collected into a container to take to and during cleaning/de-oiling. This reduces exposure to fluids during transport and cuts from sharps. It can increase productivity by using bulk handling rather than single components to be moved;
   - close fitting rubber gloves should be worn when components need to be handled.

4. For micro-firms, where the cost of implementing the above may be greater than the benefit, the following RMMs should be implemented:
   - operators must not put their hands into/near a moving machine. Therefore, before making adjustments or handling parts the machine should be stopped;
   - when adjusting machine operators must wear single use rubber gloves which are the correct size and close fitting;
   - when transporting machined parts operators must use a container.

The above RMMs need to be implemented into workplaces using OBMWFs with an MCCPs content >10 %. Many of the recommendations outlined above will also be relevant to those industries using products containing ≤10 % MCCPs as they will help reduce RWC exposures in these industries. They will also help to reduce RWC inhalation exposure for OBMWFs with 70% MCCPs, which had a RCR of 1.5.

Compliance with the requirements of the CAD would do much to ensure that the correct RMMs are in place for the use of OBMWFs containing MCCPs. However, as MCCPs are manufactured in >1000 tpa, REACH registration dossiers will have to be submitted by manufacturers/importers by December 2010, if they have pre-registered. As MCCPs are classified as dangerous industry will have to submit exposure scenarios, including appropriate RMMs, with their registration dossier. To do this they will have to carry out an iterative process to ensure exposures are reduced to an acceptable level (i.e. the RCR should be below 1). Therefore, for industry to achieve an RCR less than 1 for OBMWFs with an MCCPs content >10 % their exposure scenarios and extended safety data sheets will need to include (as a minimum) the RMMs proposed above.

Industry commented on the draft Annex XV report and agreed to 'give very serious consideration to the control measures suggested' (Pers. comm., 2008). They also state that they hope 'to obtain [a] more direct measure of dermal exposure to MCCPs' (Pers. comm., 2008) to reduce uncertainties in the human exposure assessment. This in turn should be reflected in the RCRs and the subsequent risk management decisions. Although, the producers of MCCPs have had an opportunity to comment on these recommendations they have not had the opportunity (due to the time constraints involved in producing this Annex XV report) to consult with those down the supply chain (formulators, end-users) to see if these measures could be implemented. The producers have indicated that they will consult on these proposals during the compilation of their REACH registration dossiers and include the appropriate RMMs (which may include those outlined above) into their Chemical Safety Reports (Pers. comm., 2008). Therefore, providing that the above RMMs are consulted on and information on this consultation is provided within the REACH registration document then no further action needs to be taken at this time. However, if this is not the case then a partial restriction (to only allow use of the product in enclosed systems) would be the appropriate way forward.

B.10.2 Environment

The following section considers the risks arising from the updated exposure assessment described in Section B.9.5 plus the other uses assigned a conclusion (iii). The information is also detailed in Section 2.4 of Annex 1.

B.10.2.1 Surface water

The PNEC for surface water is 1 µg/l (EC, 2005).

The PECs and PEC/PNECs covering the use of metalworking fluids, recycling/recovery of metal working fluids, the use of MCCPs in PVC and in the conversion for rubber/polymers (other than PVC) are shown in Table 10.3.

Table 10.3 PECs and PEC/PNEC ratios for surface water

Scenario		PEC (µg/l)	PEC/PNEC
Metal working / cutting	Formulation	1.64	**1.64**
	Use in oil-based fluids (large facility)	0.71	0.71
	Use in oil-based fluids (small facility)	0.66	0.66
	Use in emulsifiable fluids	0.15	0.15
	Use in emulsifiable fluids – intermittent release	46.60	**46.60**
	Recycling/recovery of metal working fluids – waste transfer facility	0.10	0.10
	Recycling/recovery of metal working fluids – physico-chemical treatment facility	0.15	0.15
	Recycling/recovery of metal working fluids – oil re-refining facility	0.17	0.17
Use in PVC – plastisol coating[1, 2]	Compounding – O	0.15 [0.15]	0.15 [0.15]
	Conversion – O	0.44 [0.26]	0.44 [0.26]
	Compounding/ conversion - O	0.49 [0.30]	0.49 [0.30]
Use in PVC – extrusion/other[1, 2]	Compounding – O	0.27 [0.22]	0.27 [0.22]
	Compounding – PO	1.03 [0.73]	**1.03** [0.73]
	Compounding – C	0.18 [0.15]	0.18 [0.15]
	Conversion – O	0.62 [0.34]	0.62 [0.34]
	Conversion - PO	0.66 [0.36]	0.66 [0.36]
	Conversion – C	0.15 [0.12]	0.15 [0.12]
	Compounding/ conversion - O	0.79 [0.46]	0.79 [0.46]
	Compounding/ conversion – PO	1.59 [0.99]	**1.59** [0.99]
	Compounding/ conversion - C	0.23 [0.15]	0.23 [0.15]
Rubber/polymers (other than PVC)	Compounding	0.19	0.19
	Conversion	0.39	0.39
	Compounding/conversion	0.48	0.48
Regional sources		0.1	0.1

Notes: 1 - O: Open systems; PO: Partially open systems; C: Closed systems (as defined in OECD (2004)).

2 - Estimates based on the properties of a 45% wt. Cl MCCPs. The equivalent estimates for a less volatile 52% wt. Cl MCCPs are given in square brackets.

As can be seen from Table 10.3, all of the scenarios for recycling/recovery of metal working fluids and in the conversion of rubber and polymers (other than PVC) lead to a PEC/PNEC ratio below one and so it can be concluded that the risk to surface water is low.

For the formulation and intermittent release of emulsifiable metal working fluids the exposures to surface water give cause for concern. For other uses of metal working fluids the risks to surface water are considered to be low.

For PVC, the conclusion from EC (2005) was that there was a risk to surface water from use in the production of PVC in some processes, particularly where compounding or compounding and conversion are carried out in partially open systems. The new analysis still identifies a PEC/PNEC ratio slightly above one (i.e. a risk) for these two scenarios. All other PVC scenarios lead to a PEC/PNEC ratio below one (low risk).

B.10.2.2 Sediment

The PNEC for sediment for MCCPs is 5 mg/kg wet weight (EC, 2005). The PECs and PEC/PNEC ratios for the scenarios covering the recycling/recovery of metal working fluids, formulation and use of MCCPs, in the conversion of rubber and polymers (other than PVC) and the use of MCCPs in PVC are shown in Table 10.4.

All of the scenarios for recycling/recovery of metal working fluids lead to a PEC/PNEC ratio below one and so it can be concluded that the risk to sediment from this option is low. The formulation and use of metal working fluids (except use in emulsifiable fluids) indicates that there is a risk to sediment.

For the conversion of rubber and polymers (other than PVC) there is no risk from compounding. However, a risk still remains for this use in conversion and compounding/conversion.

For PVC, the conclusion from EC (2005) was that there was a risk to freshwater sediment from use in the production of PVC in the following scenarios:

- Use in PVC: plastisol coating – conversion sites or sites carrying out both compounding and conversion.
- Use in PVC: extrusion/other – compounding sites using partially open processes or sites carrying out both compounding and conversion using open, partially open or closed processes.
- Use in PVC: extrusion/other – conversion sites using open, partially open or closed processes.

The new analysis indicates that compounding and conversion sites using closed processes are likely to be well controlled and as a result the

PEC/PNEC ratios for PVC conversion sites using closed processes and sites carrying out both compounding and conversion using closed processes are now expected to be below one (low risk). The risk characterisation ratios for the remaining PVC scenarios are broadly similar to those determined previously.

Table 10.4 PECs and PEC/PNEC ratios for sediment

Scenario		**PEC (mg/kg wet wt.)**	**PEC/PNEC**
Metal working / cutting	Formulation	21	**4.20**
	Use in oil-based fluids (large facility)	8.1	**1.62**
	Use in oil-based fluids (small facility)	8.45	**1.69**
	Use in emulsifiable fluids	1.9	0.38
	Use in emulsifiable fluids – intermittent release	595 or 11.7	**119 or 2.34**[3]
	Recycling/recovery of metal working fluids – waste transfer facility	1.33	0.27
	Recycling/recovery of metal working fluids – physico-chemical treatment facility	1.95	0.39
	Recycling/recovery of metal working fluids – oil re-refining facility	2.19	0.44
Use in PVC – plastisol coating[1, 2]	Compounding – O	1.88 [1.88]	0.38 [0.38]
	Conversion – O	5.68 [3.35]	**1.14** [0.67]
	Compounding/ conversion - O	6.28 [3.90]	**1.26** [0.70]
Use in PVC – extrusion/other[1, 2]	Compounding – O	3.47 [2.78]	0.69 [0.56]
	Compounding – PO	13.2 [9.37]	**2.64** [**1.87**]
	Compounding – C	2.29 [1.97]	0.46 [0.39]
	Conversion – O	7.95 [4.38]	**1.59** [0.87]
	Conversion - PO	8.42 [4.61]	**1.68** [0.92]

Scenario		PEC (mg/kg wet wt.)	PEC/PNEC
	Conversion – C	1.89 [1.57]	0.38 [0.31]
	Compounding/ conversion - O	10.1 [5.9]	**2.02** [**1.18**]
	Compounding/ conversion – PO	20.3 [12.7]	**4.06** [**2.54**]
	Compounding/ conversion - C	2.90 [1.85]	0.58 [0.37]
Rubber/polymers (other than PVC)	Compounding	2.2	0.48
	Conversion	5	**1.00**
	Compounding/conversion	6.15	**1.23**
Regional sources		0.7	0.14

Notes: 1 - O: Open systems; PO: Partially open systems; C: Closed systems (as defined in OECD (2004)).
2 - Estimates based on the properties of a 45% wt. Cl MCCPs. The equivalent estimates for a less volatile 52% wt. Cl MCCPs are given in square brackets.
3 – Intermittent release scenario – the risk assessment indicates that it is not clear how this is dealt with in the TGD for sediment

B.10.2.3 Sewage treatment processes

The PNEC for sewage treatment microorganisms is 80 mg/l (EC 2005). All of the PECs in EC (2005) were well below this level, and the same is also true for the refined scenarios here. Therefore, as was the case in EC (2005) the risk to sewage treatment processes from all uses of MCCPs is expected to be low.

B.10.2.4 Terrestrial compartment

The PNEC for MCCPs for the terrestrial compartment is 10.6 mg/kg wet wt. The PECs and PEC/PNEC ratios for the scenarios covering the formulation and use of metal working fluids, recycling/recovery of metal working fluids, conversion of rubber and polymers (other than PVC) and the use of MCCPs in PVC are shown in Table 10.5.

All of the scenarios for recycling/recovery of metal working fluids and conversion of rubber and polymers (other than PVC) lead to a PEC/PNEC ratio below one and so it can be concluded that the risk to soil is low.

For the formulation and intermittent release from the use of emulsifiable metal working fluids it can be concluded that there is a risk to soil. For the other uses of metal working fluids the risks are considered to be low.

For the use in PVC, EC (2005) identified a PEC/PNEC ratio above one for the following scenario only (all other PVC scenarios were low risk):

- Use in PVC: extrusion/other – sites carrying out both compounding and conversion using partially open systems.

The analysis here still identifies a PEC/PNEC ratio above one for this scenario. Again, the PEC/PNEC ratios for all other PVC scenarios are still below one.

Table 10.5 PECs and PEC/PNEC ratios for soil

Scenario		**PEC (mg/kg wet wt.)**	**PEC/PNEC**
Metal working / cutting	Formulation	14.1	**1.33**
	Use in oil-based fluids (large facility)	5.6	0.53
	Use in oil-based fluids (small facility)	5.08	0.48
	Use in emulsifiable fluids	0.53	0.05
	Use in emulsifiable fluids – intermittent release	46	**4.34**[4]
	Recycling/recovery of metal working fluids – waste transfer facility	0.12	0.01
	Recycling/recovery of metal working fluids – physico-chemical treatment facility	0.57	0.05
	Recycling/recovery of metal working fluids – oil re-refining facility	0.75	0.07
Use in PVC – plastisol coating[1, 2]	Compounding – O	0.52 [0.52]	0.05 [0.05]
	Conversion – O	3.29 [1.59]	0.31 [0.15]
	Compounding/ conversion - O	3.72 [1.99]	0.35 [0.19]
Use in PVC – extrusion/other[1, 2]	Compounding – O	1.68 [1.88]	0.16 [0.18]
	Compounding – PO	8.73 [5.96]	0.82 [0.56]
	Compounding – C	0.82 [0.59]	0.08 [0.06]
	Conversion – O	4.93 [2.34]	0.47 [0.22]

Scenario		PEC (mg/kg wet wt.)	PEC/PNEC
	Conversion - PO	5.28 [2.51]	0.50 [0.24]
	Conversion – C	0.53 [0.30]	0.05 [0.03]
	Compounding/ conversion - O	6.52 [3.44]	0.62 [0.32]
	Compounding/ conversion – PO	13.9 [8.37]	**1.31** [0.79]
	Compounding/ conversion - C	1.26 [0.50]	0.12 [0.05]
Rubber/polymers (other than PVC)	Compounding	0.85	0.08
	Conversion	2.76	0.26
	Compounding/conversion	3.5	0.33
Regional sources		0.088	0.01

Notes: 1 - O: Open systems; PO: Partially open systems; C: Closed systems (as defined in OECD (2004)).
2 - Estimates based on the properties of a 45% wt. Cl MCCPs. The equivalent estimates for a less volatile 52% wt. Cl MCCPs are given in square brackets.

B.10.2.5 Atmosphere

No significant exposures or effects are expected, so risks are assumed to be low from all scenarios.

B.10.2.6 Secondary poisoning

The PNEC for secondary poisoning from MCCPs is 10 mg/kg food (ECB 2007). The PECs and PEC/PNEC ratios for the scenarios covering the use of metalworking fluids, recycling/recovery of metal working fluids, conversion of rubber and polymers (other than PVC) and the use of MCCPs in PVC are shown in Tables 10.6 (fish food chain) and 10.7 (earthworm food chain).

Table 10.6 PECs and PEC/PNEC ratios for secondary poisoning via the fish food chain

Scenario		PEC (mg/kg wet wt.)[3]	PEC/PNEC
Metal working / cutting	Formulation	1.6-3.2	0.16–0.32
	Use in oil-based fluids (large facility)	0.76-1.52	0.076–0.152
	Use in oil-based fluids (small facility)	0.72-1.44	0.072–0.144
	Use in emulsifiable fluids	0.26-0.53	0.026–0.053
	Use in emulsifiable fluids – intermittent release	1.04-2.08	0.104–0.208
	Recycling/recovery of metal working fluids – waste transfer facility	0.22-0.44	0.02-0.04
	Recycling/recovery of metal working fluids – physico-chemical treatment facility	0.26-0.52	0.03-0.05
	Recycling/recovery of metal working fluids – oil re-refining facility	0.28-0.56	0.03-0.06
Use in PVC – plastisol coating[1, 2]	Compounding – O	0.26-0.52 [0.26-0.52]	0.03-0.05 [0.03-0.05]
	Conversion – O	0.52-1.04 [0.36-0.72]	0.05-0.10 [0.04-0.07]
	Compounding/ conversion - O	0.56-1.12 [0.40-0.80]	0.06-0.11 [0.04-0.08]
Use in PVC – extrusion/other[1, 2]	Compounding – O	0.38-0.76 [0.32-0.64]	0.04-0.08 [0.03-0.06]
	Compounding – PO	1.04-2.08 [0.78-1.56]	0.10-0.21 [0.08-0.16]
	Compounding – C	0.28-0.56 [0.26-0.52]	0.03-0.06 [0.03-0.05]
	Conversion – O	0.68-1.36 [0.44-0.88]	0.07-0.14 [0.04-0.09]
	Conversion - PO	0.72-1.44 [0.46-0.92]	0.07-0.14 [0.05-0.09]
	Conversion – C	0.26-0.52 [0.24-0.48]	0.03-0.05 [0.02-0.05]
	Compounding/ conversion - O	0.84-1.68 [0.54-1.08]	0.08-0.17 [0.05-0.11]
	Compounding/	1.54-3.08	0.15-0.31

Scenario		PEC (mg/kg wet wt.)[3]	PEC/PNEC
	conversion – PO	[1.02-2.04]	[0.10-0.20]
	Compounding/ conversion - C	0.34-0.68 [0.26-0.52]	0.03-0.07 [0.03-0.05]
Rubber/polymers (other than PVC)	Compounding	0.3-0.60	0.030-0.060
	Conversion	0.48-0.96	0.048-0.096
	Compounding/conversion	0.56-1.12	0.056-0.112

Notes: 1 - O: Open systems; PO: Partially open systems; C: Closed systems (as defined in OECD (2004)).
2 - Estimates based on the properties of a 45% wt. Cl MCCPs. The equivalent estimates for a less volatile 52% wt. Cl MCCPs are given in square brackets.
3 - Calculation includes a food accumulation factor of 1-3 (see ECB (2007)).

All of the scenarios for the use of metalworking fluids, recycling/recovery of metal working fluids and the conversion of rubber and polymers (other than PVC) lead to a PEC/PNEC ratio below one and so it can be concluded that the risk from this option is low.

For use in PVC, all of the PEC/PNEC ratios for the fish food chain are below one, indicating a low risk to the environment for this food chain. This is the same as the conclusion reached in ECB (2007).

Table 10.7 PECs and PEC/PNEC ratios for secondary poisoning via the earthworm food chain

Scenario		**PEC (mg/kg wet wt.)[3]**	**PEC/PNEC**
Metal working / cutting	Formulation	39.7	**3.97**
	Use in oil-based fluids (large facility)	16.1	**1.61**
	Use in oil-based fluids (small facility)	14.7	**1.47**
	Use in emulsifiable fluids	1.4	0.14
	Use in emulsifiable fluids – intermittent release	129	**12.9**[4]
	Recycling/recovery of metal working fluids – waste transfer facility	0.5	0.05
	Recycling/recovery of metal working fluids – physico-chemical treatment facility	1.7	0.17
	Recycling/recovery of metal working fluids – oil re-refining facility	2.1	0.21
Use in PVC – plastisol coating[1, 2]	Compounding – O	1.56 [1.56]	0.16 [0.16]
	Conversion – O	8.64 [4.30]	0.86 [0.43]
	Compounding/ conversion - O	9.74 [5.32]	0.97 [0.53]
Use in PVC – extrusion/other[1, 2]	Compounding – O	4.52 [3.24]	0.45 [0.32]
	Compounding – PO	22.6 [15.5]	**2.26** [**1.55**]
	Compounding – C	2.33 [1.73]	0.23 [0.17]
	Conversion – O	12.8 [6.20]	**1.28** [0.62]
	Conversion - PO	13.7 [6.65]	**1.37** [0.67]
	Conversion – C	1.58 [0.98]	0.16 [0.10]
	Compounding/ conversion - O	16.9 [9.03]	**1.69** [0.90]
	Compounding/	35.8	**3.58**

Scenario		PEC (mg/kg wet wt.)[3]	PEC/PNEC
	conversion – PO	[21.6]	[**2.16**]
	Compounding/ conversion - C	3.46 [1.51]	0.35 [0.15]
Rubber/polymers (other than PVC)	Compounding	2.7	0.27
	Conversion	8.8	0.78
	Compounding/conversion	10	**1.00** [4]

Notes: 1 - O: Open systems; PO: Partially open systems; C: Closed systems (as defined in OECD (2004)).

2 - Estimates based on the properties of a 45% wt. Cl MCCPs. The equivalent estimates for a less volatile 52% wt. Cl MCCPs are given in square brackets.

3 - As well as the differences in the emission estimates, there are also some small, but marked, differences in the PEC estimates here compared with those in EC (2005). This results from the fact that EUSES 2.0.3 was used for the calculations in this report, but EUSES 1.0 was used for the calculations in EC (2005). The same earthworm bioaccumulation factor has been used in both methods. This is discussed further in ECB (2007).

4 - PEC/PNEC ratios for conversion of rubber and polymers (other than PVC) are less than 1 if a newer version of the EUSES model is used.

For the use of MCCPs in conversion of rubber and polymers (other than PVC) there is a risk (PEC/PNEC of 1) associated with compounding and conversion. If a newer model of EUSES is used the PEC/PNEC is <1. Other scenarios for conversion of rubber and polymers indicated that the risk for the earthworm food chain is acceptable.

There is a risk associated with the earthworm food chain associated with the formulation and use of MWF (except use of emulsifiable MWFs).

For the earthworm food chain, ECB (2007) identified a PEC/PNEC above one for the following scenarios for PVC:

- Use in PVC – plastisol coating – combined compounding/conversion sites. The risk identified depended on whether EUSES 1 or EUSES 2.0.3 was used for the calculation (the PEC/PNEC ratio was 1.04 based on the EUSES 1 calculation and 0.97 based on EUSES 2.0.3).
- Use in PVC – extrusion/other – compounding sites using partially open systems.
- Use in PVC – extrusion/other – conversion sites and combined compounding/conversion sites.

The new analysis indicates that the risk characterisation ratios from conversion sites using closed processes and those from combined compounding/conversion sites using closed processes would now be below one, indicating a low risk from these scenarios. The risk characterisation ratios for the remaining PVC scenarios are broadly similar to those determined previously.

B.10.2.7 Marine compartment

No PNECs were derived for the marine environment in either EC (2005) or ECB (2007) and no risk characterisation for the marine environment was carried out in these reports. Therefore the PEC/PNEC ratios for the marine environment have not been considered here for the new and revised scenarios.

B.11 Summary on hazard and risk

Human health

Oil-based metal working fluids

MCCPs have been classified as R64 (May cause harm to breast-fed babies) and R66 (Repeated exposure may cause skin dryness or cracking). For the purposes of this transition dossier DNELs have been calculated for the health endpoints and routes of exposure that were relevant to the worker exposure situations of concern (conclusion iii) identified in the RAR. These are 1.6 mg/m^3 (8h-TWA) long-term inhalation DNEL and 11.5 mg/kg/day long-term dermal DNEL.

These values were then compared with the RWC and typical exposure values to work out the RCRs for this exposure scenario. The RCRs for all RWC and typical exposures, except the RWC inhalation exposure for a 10 % MCCPs product and the typical dermal exposure for a 10 % product, show that the risks are not adequately controlled (RCR >1). If, the combined exposure for an OBMWF with a 10 % MCCPs content had been derived from the typical dermal and RWC inhalation exposure the RCR indicates that the risks are adequately controlled (RCR <1).

Despite the uncertainties associated with the dermal exposure data there is a need to reduce the potential risks for workers being exposed to OBMWFs containing MCCPs at >10 %. Therefore, the following stepwise approach should be taken by industry to reduce both dermal and inhalation exposure when MCCPs are used in OBMWFs at >10 %. This approach mirrors what companies **should already** be doing in order to follow the principles of good practice as required by CAD.

1. Where practical MCCPs in OBMWFs should be substituted with an alternative substance of lower hazard and risk. If it is not possible to substitute industry should justify in their risk assessments why the alternatives (some of which are outlined in Section C) are not suitable for the specific process they are carrying out.

2. Where there is continuous use of OBMWFs containing >10 % MCCPs all the following RMMs must be put in place and followed:
    - the process should be enclosed;
    - autofeed of the parts;
    - autocollection of the parts;
    - components should be collected into a container to take to and during cleaning/de-oiling. This reduces exposure to fluids during transport and cuts from sharps. It can increase productivity by using bulk handling rather than single components to be moved;
    - when dealing with concentrates a pump should be used to transfer the substance for dilution. Using a pump will ensure that concentrates are not poured and this will prevent spillage, prevent skin contact with the concentrate and prevent splashing.

3. Where there is frequent use (i.e. some use every day but it is not continuous) of OBMWFs containing >10 % MCCPs the following RMMs should be put in place:
    - a foot operated solenoid should be used to control the flow of MWF, i.e. fluid only flows when the 'cutting' is in progress. Operators should not put their hands near the tool when 'cutting' is in progress. This will prevent hands becoming soaked in wet fluid when dealing with tools and workpieces on the tool. There are cost benefits to doing this; fluid aerosols are not created, wastage of MWFs is reduced, mixing with oxygen is reduced thus giving longer life;
    - splash guard at the machine;
    - components should be collected into a container to take to and during cleaning/de-oiling. This reduces exposure to fluids during transport and cuts from sharps. It can increase productivity by using bulk handling rather than single components to be moved;
    - close fitting rubber gloves should be worn when components need to be handled.

4. For micro-firms, where the cost of implementing the above may be greater than the benefit, the following RMMs should be implemented:
    - operators must not put their hands into/near a moving machine. Therefore, before making adjustments or handling parts the machine should be stopped;
    - when adjusting machine operators must wear single use rubber gloves which are the correct size and close fitting;
    - when transporting machined parts operators must use a container.

The above RMMs need to be implemented into workplaces using OBMWFs with an MCCPs content >10 %. Many of the recommendations outlined above will also be relevant to those industries using products containing ≤10 % MCCPs.

Compliance with the requirements of the CAD would do much to ensure that the correct RMMs are in place for the use of OBMWFs containing MCCPs. However, as MCCPs are manufactured in >1000 tpa, REACH registration dossiers will have to be submitted by manufacturers/importers by December 2010, if they have pre-registered. As MCCPs are classified as dangerous industry will have to submit exposure scenarios, including appropriate RMMs, with their registration dossier. To do this they will have to carry out an iterative process to ensure exposures are reduced to an acceptable level (i.e. the RCR should be below 1). Therefore, for industry to achieve an RCR less than 1 for OBMWFs with an MCCPs content >10 % their exposure scenarios and extended safety data sheets will need to include (as a minimum) the RMMs proposed above.

Industry commented on the draft Annex XV report and agreed to 'give very serious consideration to the control measures suggested' (Pers. comm., 2008). They also state that they hope 'to obtain [a] more direct measure of dermal exposure to MCCPs' (Pers. comm., 2008) to reduce uncertainties in the human exposure assessment. This in turn should be reflected in the RCRs and the subsequent risk management decisions. Although, the producers of MCCPs have had an opportunity to comment on these recommendations they have not had the opportunity (due to the time constraints involved in producing this Annex XV report) to consult with those down the supply chain (formulators, end-users) to see if these measures could be implemented. The producers have indicated that they will consult on these proposals during the compilation of their REACH registration dossiers and include the appropriate RMMs (which may include those outlined above) into their Chemical Safety Reports (Pers. comm., 2008). Therefore, providing that the above RMMs are consulted on and information on this consultation is provided within the REACH registration document then no further action needs to be taken at this time. However, if this is not the case then a partial restriction (to only allow use of the product in enclosed systems) would be the appropriate way forward.

Environment

The following conclusions on the RMMs appropriate for the exposure scenarios of concern for the environment are outlined below. For full details on how these conclusions were reached reference should be made to Annex 1. The information below includes the update to the exposure assessment (described in Section B.9.5) for recycling/recovery of metal working fluids and their use in PVC.

Use of emulsifiable metal working fluids

The risks of the use of emulsifiable fluids on the environment are considered to be adequately controlled (all PEC/PNEC ratios are <1).

The identified risk relates to intermittent releases of large quantities of MCCPs in emulsifiable metalworking fluids. In addition, new scenarios have been developed to investigate the possible risks to the environment from one option that was considered during the development of the Annex XV report for the use of MCCPs in metal working fluids. This considers the use of closed machinery whereby the emissions from the site of use can be controlled and the spent/waste metal cutting fluids can be sent for recovery/recycling (i.e. waste transfer facility). No risks to the environment were identified from these scenarios.

Based on the current information it is concluded that the most appropriate option for use of MCCPs in emulsifiable metalworking fluids is to ensure that legislation is in place to prevent the intermittent release of large quantities of emulsifiable fluids containing MCCPs (e.g. though ensuring that such wastes are properly disposed of).

Whilst existing legislation (such as the Waste Oils Directive, 75/439/EEC) effectively includes a requirement that should prevent releases such as this, this practice cannot be ruled out; it has been acknowledged that the Directive has not been well implemented and that waste oil collection rates remain too low. The new Directive on Waste appears to provide a means by which Member States would be required to ensure that risks to the environment are addressed (see Section 3.8 of Annex 1).

If this measure is successful in addressing the intermittent release scenario, there will no longer be a concern for use in emulsifiable metalworking fluids and so wider restrictions on use of MCCPs in this application are not considered to be the most appropriate risk reduction option on the basis of the PEC/PNEC ratios approach.

Use of oil-based metal working fluids

The exposure scenarios concluded that there is no risk (PEC/PNEC ratios range from 0.48 to 0.71) from the use of OBMWF in small and large facilities to surface water, soil and via the fish food chain. However, there is a risk from both small and large facilities to sediment and via the earthworm food chain (PEC/PNEC ratios >1). If recycling/recovery of MWFs occurs then the risks are expected to be low.

For oil-based metalworking fluids, the most appropriate means of control is considered to be through the IPPC Directive (this will only cover certain larger installations) and the Water Framework Directive. The new Directive on waste (as discussed above) should also ensure that the risks to the environment are addressed.

Given the available information on alternatives to MCCPs, it is concluded that restrictions on the marketing and use of MCCPs in this application is not the most appropriate option at the current time based on the PEC/PNEC ratios approach to assessment of the risks. This is because:

- Whilst use of alternative metalworking fluids or alternative production techniques has been shown to be possible in certain applications, evidence from a wide range of sources suggests that substitution in certain extreme pressure applications is not technically feasible while preserving the desired properties of the end product. It has not been possible to draw up a comprehensive list of applications where this is the case but those identified as potentially falling into this category include deep drawing; punching; extrusion; pilgering; forming; drilling; tapping; rimming; threading; boring; and broaching.

- Whilst there is a wide range of potential alternatives to MCCPs that may be used for certain applications, the available information suggests that these may have properties that could pose significant risks to health and/or the environment.

Formulation of metal working fluids

The environmental exposure scenarios indicate that there are risks to the environment (surface water, sediment, soil and earthworm food chain) from the formulation of metal working fluids (PEC/PNEC ratios range from 1.33 to 4.20). If recycling/recovery following the formulation of MWFs occurs then the risks are expected to be low.

As discussed above, for the use of OBMWFs, the most appropriate means of control is considered to be through the IPPC Directive (this will only cover certain larger installations) and the Water Framework Directive. The new Directive on waste (as discussed above) should also ensure that the risks to the environment are addressed.

PVC

Impact of new information

One key piece of new information was that emission controls (exhaust recovery and incineration) are now known to be in place at all PVC conversion sites in the EU. This has been taken into account in the revised emission estimates. The major impact of this is on the scenarios for conversion sites using closed systems (and hence the scenario for sites carrying out both compounding and conversion) where the PEC/PNEC ratios are <1.

It should be noted that the presence of emission controls was already included in the emission estimates for sites carrying out conversion using open or partially open systems and so this new information has had limited impact on the PECs and hence PEC/PNEC ratios for these scenarios. This would result in a change of conclusion such that risks are no longer identified for the following scenarios:

Sediment

- Use in PVC – extrusion/other - conversion sites using closed processes and combined compounding/conversion sites using closed processes.

Secondary poisoning (earthworm food chain)

- Use in PVC – extrusion/other - conversion sites using closed processes and combined compounding/conversion sites using closed processes.

Although the presence of emission controls was already assumed in the PEC estimates at conversion sites using open or partially open systems, it is possible that the actual efficiency of the equipment in plants may be higher than assumed here (leading to a lower emission). However there is currently insufficient information on the emissions of MCCPs from processes using such equipment to allow more refined emission estimates to be made.

It should also be noted that some of the emissions during raw materials handling (e.g. losses from spillage) are also not affected by the presence of emission controls at conversion sites.

Overall conclusion for PVC

For use of MCCPs in PVC the risks (PEC/PNEC ratios <1) in the following uses are considered to be low:

- PVC – plastisol coating – open compounding
- PVC – extrusion/other – open compounding
- PVC – extrusion/other – closed compounding
- PVC – extrusion/other – closed conversion
- PVC – extrusion/other – closed conversion/compounding

There are outstanding risks (PEC/PNEC ratios >1) associated with MCCPs in the following uses of PVC:

- PVC – plastisol coating – open conversion
- PVC – plastisol coating – open conversion/compounding
- PVC – extrusion/other – partially open compounding
- PVC – extrusion/other – open conversion
- PVC – extrusion/other – partially open conversion
- PVC – extrusion/other – open conversion/compounding
- PVC – extrusion/other – partially open conversion/compounding

It is considered that the approach representing the most appropriate balance of advantages and drawbacks to control the risks to the environment would be to ensure that emissions are controlled to an adequate level through inclusion of MCCPs as a priority substance under the Water Framework Directive (with subsequent measures to set and achieve an Environmental Quality Standard (EQS)) and control of emissions from those (larger) installations covered by the IPPC Directive in accordance with the conclusions of the risk assessment.

These measures could be expected to significantly reduce emissions of MCCPs below the levels identified in the risk assessment. The costs of implementing these measures for operators are estimated to be significantly less than for replacement under REACH restrictions. Moreover, this approach would not (directly) introduce additional risks associated with the use of substitutes, several of which are also have concerns in relation to environmental impacts.

However, this does not take into account the implications for environmental risks if MCCPs are determined to have PBT properties and this is considered in more detail in Section 6.4 of Annex 1.

Uses where only a plasticising effect is required

In applications where MCCPs are used primarily for their plasticising properties, there are available alternatives that could be used which appear to pose lower risks for the environment (e.g. DINP). Such alternatives will generally be considerably more expensive than MCCPs. However, the economic impact of substitution is not the only factor that needs to be taken into account in determining the most appropriate risk reduction strategy.

Information collated for this risk reduction strategy suggests that it is possible to control releases of MCCPs to the environment to a level where it could reasonably be expected that there would no longer be a need for limiting the risks (i.e. PEC/PNEC ratio <1; given that the realistic worst case assessment suggests that PEC/PNEC ratios are relatively low compared to some uses); as practices vary amongst sites. It is concluded that, if measures are taken to ensure that this achieved through the Water Framework Directive, for example, these risks could be addressed in a more proportionate manner.

Uses where flame retardancy is required

In relation to control of the identified risks, the same conclusions as apply to uses where MCCPs are used primarily for their plasticising effects also apply to uses where they are used for their flame retardant properties.

However, with regard to the implications of possible replacement of MCCPs, the available information suggests that the drawbacks of a possible restriction would be more significant for these uses. In particular:

- The economic implications of substitution would be expected to be significantly greater, due to the types of substances that would be required in order to achieve the same degree of flame retardancy.
- Whilst the available information on alternatives to MCCPs is less complete than that for MCCPs themselves, the information that is available suggests that identified alternatives may not lead to a significant reduction in risks (e.g. preliminary PEC/PNEC ratios aryl phosphates are in several cases much higher than for MCCPs).

Losses during the service life of products

Whilst the risk assessment does not identify a specific need for limiting the risks associated with losses of MCCPs from PVC products during their service life, such releases may potentially be significant. This issue is potentially important in the context of the possible PBT properties of MCCPs, as described below.

Rubber and polymers other than PVC

Given that the total emissions from this sector are low, the highest PEC/PNEC ratio identified is only 1.23 and the potentially high costs of substituting MCCPs, it is concluded that the most appropriate controls for this use are for appropriate emission limit values to be introduced (where this is not already the case) under the IPPC regime and for controls to be introduced on discharges, emissions and losses through recommendation that MCCPs be included on the priority list of substances under the Water Framework Directive (see above).

As with PVC, there is the potential for quite significant releases from these products during their service life. Whilst the risk assessment does not identify a specific need for limiting the risks associated with losses of MCCPs from rubber/other polymer products during their service life, such releases may potentially be significant. This issue is potentially important in the context of the possible PBT properties of MCCPs, as described below.

Waste remaining in the environment

For 'waste remaining in the environment' it is concluded that there is insufficient certainty with regard to the risk assessment conclusions to draw firm conclusions on the most appropriate risk reduction measures.

Therefore, no additional measures are considered appropriate for these uses based on the risks identified using the PEC/PNEC approach.

Overall conclusions for Risk Management Measures for the environment

The proposals for controlling the outstanding risks associated with the use of MCCPs in the environment, which are considered to be proportionate, are detailed in Table 11.1.

Table 11.1 Proposals for limiting the risks associated with the use of MCCPs

Use	Marketing and Use	Integrated Pollution Prevention and Control	Water Framework Directive	Waste oils	No additional measures
Formulation and use of metal cutting/working fluids		✓	✓	✓	
Use in Polyvinyl chloride (PVC) compounding and conversion		✓	✓		
Use in conversion of rubber and polymers other than PVC			✓		
Waste remaining in the environment					✓

The above discussion relates to measures that are concluded to be appropriate to address the environmental risks associated with MCCPs based on the uses for which a need for limiting the risks has been identified using the PEC/PNEC ratios approach. It is considered that the measures identified above represent the best balance of advantages and drawbacks for society as a whole, taking into account the level of risk identified based on those PEC/PNEC ratios.

However, the updated (November, 2008) version of the environmental RRS (Annex 1) also concludes that consideration may need to be given to further action to address MCCPs once the results of the PBT assessment is known.

Work on determining the potential PBT properties of MCCPs is still underway and is not expected to be complete before 2009.

If ongoing testing concludes that MCCPs is a PBT substance then further consideration needs to be given to what is the most appropriate risk management measure.

C. AVAILABLE INFORMATION ON ALTERNATIVES

C.1 Identification of possible alternative substances and techniques for oil-based metal working fluids

C.1.1 Introduction

The purpose of metalworking fluids is to remove deformation heat and friction heat that arises during metal cutting. They additionally flush away chips and prevent dusting. Extreme pressure (EP) additives are added to metalworking fluids in order to enhance lubrication and surface finish during metal cutting/grinding and forming applications. Typical EP additives contain organic compounds of chlorine, sulphur and/or phosphorus. Lubrication properties depend on a number of parameters namely temperature, friction, speed of machining and viscosity. The choice of EP additives partly depends on the work process and on the type of metal.

MCCPs are used in metal working/cutting fluids in varied concentrations because they are multi-functional and unlike the other EP additives can be used across a wide temperature range (180°C to 420°C) and are particularly suitable for low temperature applications. The contents of MCCPs in MWF vary considerably with the task.

Further information on alternatives to OBMWFs can be found in Section 5.2 of Annex 1.

C.2 Availability of alternatives for oil-based metal working fluids

C.2.1 Overview

For the purpose of this Annex XV dossier, questionnaires were sent out to producers of metalworking lubricants through the relevant trade associations soliciting information on the availability of alternatives. With the exception of one UK-based lubricant producer, responses by the industry to this request have not been forthcoming. However, some information on the availability of alternatives to MCCPs use in OBMWFs was provided in a study conducted by Risk and Policy Analysts Ltd (RPA) on behalf of UK Chemicals Stakeholder Forum (RPA, 2002) and in the report of the Danish Environmental Protection Agency (2005) project “Mapping and development of alternatives to chlorinated lubricants in the metal industry (KLORPARAFRI)”.

The Danish project, which was instituted to promote substitution of chlorinated paraffins in metalworking focused on heavy duty metal forming operations (such as deep drawing, punching and extrusion). Replacement of MCCPs in OBMWFs use in these processes has been considered problematic. 50 lubricants systems were identified through contact with a range of suppliers; of these, only four were considered to exhibit promising lubrication properties and were subjected to a full-scale production test.

The RPA study included consultation with relevant stakeholders and information on availability, technical implications and costs of potential substitutes. The consultation responses showed that there are varying opinions about the availability of alternatives for MCCPs in metalworking fluids with some industry experts indicating that almost 95% of applications have or will eventually find alternatives. Others are of the opinion that the quality of lubrication provided by MCCPs is at present, not matched by any known alternatives especially in certain arduous applications such as forging, deep drawing, drilling, stamping, rimming, threading, piercing and blanking. It was stated that in these applications, chlorinated paraffins have proved to be excellent in terms of performance and cost effectiveness.

Replacement of chlorinated paraffins in metal working lubricants for cutting processes of ordinary steel, copper, brass and aluminium and less demanding metal forming operations has generally been successful. However, it is reportedly difficult to find substitutes for MCCPs in chip-less processing of stainless steel and titanium.

In the two reports, compounds based on phosphorus, sulphur and overbased sulphonate species have been identified as potential chemical substitutes for chlorinated paraffins in metalworking fluids.

Phosphorus- and sulphur- based additives act like MCCPs in that they are activated by reacting with the metal surface in a temperature dependent process. The sulphides or phosphorus salt which is liberated form a film providing the lubricity and preventing the welding of the metal surfaces. Overbased sulphonates operate by a different mechanism. Overbased sulphonates contains colloidal carbonate salts (mainly of calcium) dispersed within the sulphonates which forms a film on interaction with iron that can act as a barrier between metal surfaces. This process is non-temperature dependent.

C.2.2. Phosphorus-based additives

The phosphorus compounds comprise a broad group of substances; however the phosphate esters (mono-, di-, and tri- ester compounds) are the main types employed as extreme pressure additives. Phosphites and phosphonates are also sometimes employed, and the latter are considered to have excellent performance under high temperature conditions because of their enhanced thermal stability. The organic radicals in the phosphorus additives can be either aliphatic or aromatic with the alkyl phosphates considered to be better than the aryl derivatives.

C.2.3. Sulphur-based additives

Sulphurised compounds including esters, fatty compounds and polysulphides have been identified as the most suitable family of substances to replace MCCPs in MWFs. Sulphides are solids - hence their viscosity does not change with temperature and pressure as long as their melting point is not exceeded. Additives based on sulphur operate (i.e. are activated) at high temperature ranges of 600-1000°C. Suitability of most sulphur-based lubricants for metal working applications is limited by the high temperature requirements, aggressiveness on yellow metals, the intense odour and dark colour. However, synthetic sulphurised esters lacking in these shortcomings are being researched and some have been developed. It was suggested in the RPA report that the combination of sulphurised esters with sulphonates would make good alternatives to MCCPs use in the metal working industry; but no specific information on specific sulphurised esters that could be substituted for MCCPs is available.

Polysulphides substances such as sulphurised polyisobutene, polypropylene and polystyrene have been mentioned as effective substitute for MCCPs in MWFs. These products have polysulphide bridges in which the sulphur atoms are present in labile form.

C.2.4. Overbased sulphonates

Overbased calcium and sodium sulphonates with total base number (TBN) range of 300 to 400 have been suggested as possible EP agents. Several consultees in the study conducted by RPA have suggested that when used in combination with sulphurised esters, overbased calcium sulphonates perform well as EP additives in oil-based metalworking fluids. The main drawback identified is that they attack yellow metals aggressively, much more than the sulphurised esters themselves; however, this is not a problem with materials such as stainless steel and titanium alloys. Finding alternatives to MCCPs have been considered difficult for the chip-less processing of these metal alloys. The overall consensus is that although sulphonates can function well as EP additives, especially in the presence of sulphurised esters, it cannot substitute for MCCPs in every single application. For extreme pressure and temperature conditions where staining caused by oil-based fluids is not a problem, sulphonates seem to have the potential of acting as suitable alternatives to MCCPs (RPA, 2002).

C.2.5. Zinc Dialkyl Dithiophosphate (CAS No. 2215-35-2)

Zinc dialkyl dithiophosphate (ZDDP) is a phosphorus-sulphur compound used as EP agent in anti-wear formulations for engines and also in lubricants for metal working. However, its effectiveness as a potential substitute for MCCPs in MWFs is limited because, when burnt ZDDP leaves a residue. Although burning is not intentional, it is unavoidable given the extreme pressure and temperature that prevail during processes requiring EP fluids. Removal of ash deposited on the metal would cause delays in the processes and increased costs (for cleaning and disposal). Another pitfall with ZDDP is that it cannot be used in arduous tasks as its EP characteristics are considered to be relatively mild. The conclusion from the RPA report is that ZDDP could be considered as only a partially suitable substitute for MCCPs, where temperature and pressure do not reach extreme levels.

C.3 Human health risks related to oil-based metal working fluids alternatives

A full assessment of the human health risks of potential substitutes is not possible as there are limited data available with which to carry out a full appraisal. Rather, an appraisal of the toxicology is provided. Most of the data presented in this section are from the RPA study and Danish EPA project which included assessment of the health and environmental properties of alternatives to MCCPs in metalworking. Some information was also obtained from internet searches and material safety data sheets on websites of lubricant manufacturers.

The potential health effects of the substances identified as substitutes for MCCPs in OBMWFs are summarised in Table C3.1.

Table C3.1 Summary of the potential health effects of alternatives

Substance group	Substance name / CAS No.	Potential health effects / Comments
Triaryl phosphates and aryl phosphites	Phenol, isopropylated, phosphate (ITAP) (3:1) / CAS No. 68937-41-7	ITAP is not irritating, sensitising or genotoxic. Moderate repeated dose toxicity (rats; dermal NOAEL: 100 mg/kg/d). No information on reprotoxicity /developmental effects/carcinogenicity
Trialkyl phosphates	Tributyl phosphate (TBP) / CAS no. 126-73-8	TBP is acutely toxic by the oral route (Xn; R22); skin irritant (Xi; R38). Limited evidence of a carcinogenic effect and classified in the EU as "Carc. Cat. 3; R40". Exposure assessments in working environment (based on EASE modelling) were performed for TBP in the Danish EPA project; the results indicate that inhalation and dermal exposures to lubricants containing TBP at common lubricant concentrations present an adverse health risks.
Dialkyl phosphates	Bis(2-ethylhexyl) hydrogen phosphate/ CAS No. 298-07-7	Corrosive to skin and mucous membrane.
Monoalkyl phosphate	2-ethylhexyl hydrogen phosphate/CAS No. 1070-03-7	Strong eye irritant; corrosive
Dialkyl phosphites	Didodecyl phosphite/ CAS No. 21302-09-0	Skin irritant
	Dimethyl hydrogen phosphite (DMHP)/ CAS No. 868-85-9	Acutely toxic (dermal; Xi/R21); eye and skin irritant; Classified by IARC as Category 3 carcinogen
Complex phosphate esters	Polyethoxy oleyether-phosphate/ CAS No. 39464-69-2	Not classified
Polysulphides	Sulphurised 2,4,4-trimethyl pentene / CAS No. 68515-88-8	Limited information available Not irritating and non-sensitising 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.
	Di-(tert-dodecyl) pentasulfide /CAS No. 31565-23-8	
Overbased calcium sulphonates	Overbased petroleum derived calcium salts of sulphonic acid /CAS No. 68783-96-0	Potential to cause inflammatory skin changes on repeated dermal application and repeated inhalation exposure in rats may cause adverse effects on the lungs.

	Overbased calcium salts of benzenesulphonic acid mono C_{15}-C_{30} branched alkyl and di-C_{11}-C_{13} branched and linear alkyl derivatives /CAS No. 71486-79-8	Information supplied by a lubricant producer for an overbased calcium sulphonates indicates that the vapour/mist has the potential to cause irritation of mucous membranes and respiratory tract and skin irritation may occur after prolonged or repeated dermal contact.
	Overbased calcium salts of benzesulphonic acid C_{14}-C_{24} branched alkyl and linear derivatives /CAS No. 115733-09-0	
Sulphur-Phosphorus compound	Zinc Dialkyl Dithiophosphate (ZDDP) / CAS No. 2215-35-2	Eye and skin irritant

C.3.1.1 Conclusions

The existing data suggest that substitution of MCCPs with some of the identified alternative substances may pose significant risk to human health. However, the available data are limited and not enough to conduct robust risk assessments. Overall, in terms of the risks to human health, no conclusion can be drawn on the suitability of the alternatives to replace MCCPs in metalworking.

C.4 Environment risks related to alternatives for use in oil-based metal working fluids

Information on the environmental risks to MCCPs in OBMWFs can be found in Section 5.2 of Annex 1.

C.5 Identification of possible alternative substances and techniques for other scenarios

Information on alternatives to MCCPs in use of PVC compounding and conversion, use in conversion of rubber and polymers (other than PVC) and any human health or environmental risks associated with them can be found in Section 5.2 of Annex 1.

C.6 Technical and economical feasibility of alternatives

C.6.1 Metal working fluids

Lubrication properties are dependent on a number of parameters such as temperature, speed of machining, friction and viscosity; consequently some lubricants would perform well in some applications and not so well in others. MCCPs are considered to be “multi-functional” EP agent in that it offers excellent performance in diverse metal cutting/forming operations. It is especially successful in slow speed machining operations and in applications where surface temperatures are limited to reduce work hardening tendencies in stainless steel and heat resistant alloys. Also, MCCPs is a relatively cheap raw material and thus it is cost effective.

It has been mentioned by several consultees in the RPA study that sulphurised esters are technically suitable as alternatives to MCCPs in metal working fluids. According to information on the website of a lubricant manufacturer, reactive sulphurised EP additives are very effective as substitute for MCCPs in OBMWFs in most slow speed machining operations where temperatures are limited and staining is not a problem. Furthermore, it is stated that in cases where staining can be a problem such as work on cuprous metals and some nickel alloys, they are inactive sulphurised additives available. However, there remain a number of applications including broaching and deep drawing where no technically suitable alternative is available.

Therefore, the RPA study concluded that substitution is difficult to achieve across the whole range of MCCPs' applications. More information and more testing of substitutes identified so far is required.

Results of the full scale production test of four promising non-chlorinated lubricants systems in the Danish EPA study suggest that a simple replacement of MCCPs with a single substance is almost technically non-viable in heavy-duty metal forming processes. None of them demonstrated satisfying lubricating performance. Thus, it was concluded that substitution of chlorinated paraffins would require extensive reformulation of the lubricant systems rather than a simple replacement of MCCPs.

Overall, based on the available information (also see Table 5.8 of Annex 1) it seems no single substance could offer the same performance and cost effectiveness achieved with MCCPs across the full spectrum of its applications in OBMWFs.

C.6.2 Use in PVC

The information presented below is given in Table 5.7 of Annex 1.

Technical feasibility:	Long-chain chlorinated paraffins (LCCPs) suitable for some applications. Phthalates (e.g. DINP) generally suitable where high fire resistance is not required. Phosphate esters broadly suitable where high fire resistance is required. These are the most suitable identified alternatives based on information available for this risk reduction strategy.

Economic feasibility:	LCCPs: perhaps 20% to 160% higher purchase price for compared to MCCPs (dependent upon application and formulation used and by analogy with other uses). Phthalates (DINP) around 60% more expensive than MCCPs. Phosphate esters significantly more expensive than MCCPs (e.g. up to 4 times price based on information in Appendix B of Annex 1, confirmed by industry (EuroChlor, 2008)) Additional costs for reformulation, product approval, etc.

C.6.3 Use in conversion of rubber and polymers (other than PVC)

The information presented below is detailed in Table 5.9 of Annex 1.

Technical feasibility	Suitable in some applications (e.g. profiles for fire-proof doors). However, reportedly use leads to a too-brittle end product in certain conveyor belts and concerns with approvals for fire resistance in bellows for buses/trains.
Economic feasibility	Industry estimates €6 million for redevelopment and testing in EU as a whole. Possible 20% increase in (ongoing) raw material costs (€375,000 per year).

C.7 Other information on alternatives

No other information on alternatives is presented within this Annex XV report.

D. Justification for action on a Community-wide basis

D.1 Considerations related to human health and environmental risks

Human Health

Across the EU, companies of all sizes (small, medium and large) are engaged in metalworking, and use OBMWFs containing MCCPs. Information on the exact tonnage of MCCPs use in OBMWFs in the EU is not available; however, according to Euro Chlor >8000 tonnes were used in formulating metal working/cutting fluids in 2006 (Euro Chlor, 2008).

The identified risks for workers during the use of MCCPs-based OBMWFs arise primarily through dermal exposure (specifically, the hands) and only limited information is available on dermal exposure to MCCPs during metalworking. It is worth noting that there are uncertainties associated with the dermal exposure values used in the risk characterisation. Dermal exposure to MCCPs in OBMWFs has been estimated from surrogate data in which MWF exposure was sampled using boron as a marker of contamination. Exposure to MCCPs was then calculated based on the mass of boron on wipe samples.

It has been shown above that if companies correctly follow the control measures prescribed in the CAD then exposure to MCCPs in OBMWFs would be adequately controlled. In order to improve the information flow to downstream users on the most appropriate RMMs to be in place when using OBMWFs, particularly those with >10% MCCPs, it is important that registrants include the RMMs in Sections B.10 and B.11 into their CSRs and extended safety data sheets.

An OEL has not been proposed as the primary human health risk comes from dermal exposure. In cases where the skin is the primary route of exposure it may be useful to consider the setting of a biological monitoring guidance value. However, there are no published studies involving biological monitoring for MCCPs. It may be possible to develop a methodology to do this but the analysis is complicated by the fact that MCCPs are a group of substances rather than a single substance. There is also a lack of suitable reference substances and a lack of internal standards.

Therefore, no action on a community wide basis has currently been proposed. However, should industry not include the RMMs proposed in Section B.10 into their CSRs then action on a community wide basis should be considered.

Environment

At present no Community wide action is proposed for the uses (metal working, PVC and rubber/polymers (other than PVC)) still considered to be of cause for concern. The discussion summarised in Section 11 (and detailed in Annex 1) considers that application of current legislation should lead to adequate control of the identified risks.

However, the updated (November, 2008) version of the environmental RRS (Annex 1) also concludes that consideration may need to be given to further action to address MCCPs once the results of the PBT assessment is known.

Work on determining the potential PBT properties of MCCPs is still underway and is not expected to be complete before 2009.

If ongoing testing concludes that MCCPs is a PBT substance then further consideration needs to be given to what is the most appropriate risk management measure.

E. Justification why a restriction is the most appropriate Community-wide measure

At present, and as discussed earlier, a restriction is not considered the most appropriate community wide action for the identified scenarios (other than for leather fat liquors where the restriction has already been agreed and will be taken forward by UK Government) at this time.

E.1 Other possible risk reduction measures

E.1.1 Human Health

As outlined in Section B.10 other RMMs have been proposed which should result in a decrease in dermal exposures. The RMMs proposed follow the principles of 'good practice' within CAD and as a first step they recommend substitution. If this cannot be achieved then the hierarchy of controls (e.g. pumps, autofeed for OBMWFs) should be put in place to reduce the potential for dermal exposure. Industry should ensure that these RMMs are included (as a minimum) as part of their exposure scenarios and extended safety data sheets within their registration dossier. If these RMMs are not recommended then a partial restriction (e.g. to only allow use of OBMWFs containing MCCPs in enclosed systems) should be considered.

E.1.2 Environment

As outlined in Annex 1 a restriction is not considered to be the most appropriate RRM at this time. Discussions on other possible risk reduction measures are detailed in Section 5.8 of Annex 1.

E.2 Comparison of instruments: restriction(s) vs. other Community-wide risk management options

A comparison of the option to restrict the use of MCCPs with other community-wide risk management options has not been considered as a restriction (other than for leather fat liquors, which has already been agreed) is not being proposed at this time.

F. Socio-economic Assessment of Proposed Restriction(s)

A socio-economic analysis has not taken place as a restriction is not being proposed at this time.

G. STAKEHOLDER CONSULTATION

The list below consists of the organisations that have been contacted by HSE and Entec for the purposes of preparing this dossier and the environmental risk reduction strategy report (see Annex 1).

Note that all of the EU Member States competent authorities for The Existing Substances Regulation have been contacted. Only those that provided information in relation to MCCPs are listed below.

Trade Associations/Industry

Association of European Manufacturers of Carbonless Paper
Akzo Nobel Coatings (Hungary)
AlphaGary
Altro
Arjo Wiggins
BLIC-European Association of the Rubber Industry
Boss Paints
British Metalforming Association
British Rubber Manufacturers Association
British Turned Parts Manufacturer Association
Caffaro
Carrs Paper
CEFIC- European Chemical Industry Council
CEPE- European Council of the Paint, Printing Ink and Artists' Colours Industry
Chance & Hunt
Chlorinated Paraffins Industry Association
Confederation of Paper Industries
CONTANCE- of National Associations of Tanners and Dressers of the European Community
Danish Paintmakers Association
Dover Chemicals
Engineering and Machinery Alliance (EAMA)
European Resilient Flooring Manufacturers Institute
European Recovered Paper Council
European Vinyls Corporation
Federation of British Electrochemical and Allied Manufacturers Association (BEAMA)
Graham & Brown
Hydro Polymers
Independent Waste paper processors Association
Ineos Chlor
International Institute of Synthetic rubber Producers
Leuna tenside
LGC limited
Machine Tool Technologies Association
Marley Floors
NCP Exports-Sentrachem
Novacke chemicke zavody

Paper Chemicals Association
PITA
Polyflor
PVC Group
Quimica del Cinca
Sandavik Materials Technology
SCL Group
Shipley Paint
Sigmakalon
Small Business Service (UK)
The Engineering Employers Federation (EEF)
The European Engineering Industry Association (ORGALIME)
UEIL- Independent Union of the European Lubricant Industry
UNIC-Italian leather Association
United Kingdom Lubricants Association (UKLA)
VSI, Germany
VVVF (Netherlands)

Competent Authorities/ Other Regulatory bodies
Australia- National Industrial Chemicals Notification and Assessment Scheme
Cyprus- Department of Labour Inspection
Denmark- Environmental Protection Agency
Environment Canada
Finland-Finnish Environment Institute
France Competent Authority- INRS and INERIS
Germany- Institute for Occupational Safety and Health
Japan-Ministry of Environment
Norway- Pollution Control Authority
Slovakia- Centre for Chemical Substances and Preparations
Sweden- National Chemicals Inspectorate
United States Environmental Protection Agency

H. OTHER INFORMATION

No further information is to be added to this Annex XV report.

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GLOSSARY

BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
bw	Body Weight
CAD	Chemical Agents Directive
CAS	Chemical Abstract Services
C&L	Classification and Labelling
Cl	Chlorine
CLP	Classification, Labelling and Packaging Regulations
CSR	Chemical Safety Report
DINP	- as quoted on p66. Please complete
DMHP	Dimethylhydrogen Phosphite
DNEL	Derived No Effects Level
DU	Downstream User(s)
EA	Environment Agency (UK)
EASE	Estimation and Assessment of Substance Exposure
EC	European Communities
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
EEC	European Economic Communities
EP	Extreme pressure
ESR	Existing Substances Regulation
EU	European Union
EUSES	European Union System for Evaluation of Substances
HCl	Hydrogen Chloride
HSE	Health and Safety Executive (UK)
IOELV	Indicative Occupational Exposure Limit Value
ITAP	Phenol, isopropylated phosphate
IUCLID	International Uniform Chemical Information Database (existing substances)
IUPAC	International Union for Pure and Applied Chemistry
LCCPs	Long Chain Chlorinated Paraffins
LOAEL	Lowest Observed Adverse Effect level
LOEC	Lowest Observed Effect Concentration
MCCPs	Medium Chain Chlorinated Paraffins
MWF	Metal working fluid
NOAEL	No Observed Adverse Effect Level
NOAEC	No Observed Adverse Effect Concentration
NOEC	No Observed Effect Concentration
OBMWF	Oil-Based Metalworking Fluid
OC	Operational Conditions
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent, Bioaccumulative and Toxic
PEC	Predicted Environmental Concentration
PM_{10}	Particulate matter 10
PNEC	Predicted No Effect Concentration
PVC	Polyvinyl Chloride

R phrases	Risk phrases according to Annex III of Directive 67/548/EEC
RAR	Risk Assessment Report
RCR	Risk Characterisation Ratio
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Management Measures
RPA	Risk Policy Analysts Ltd
RRS	Risk Reduction Strategy
RWC	Reasonable Worst Case
SCCPs	Short Chain Chlorinated Paraffins
SCOEL	Scientific Committee on Occupational Exposure Limits
S-phrases	Safety phrases according to Annex IV of Directive 67/548/EEC
SME	Small and Medium- size Enterprise
STEL	Short Term Exposure Limit
SVC	Saturated Vapour Concentration
TBN	Total base Number
TBP	Tributyl Phosphate
tpa	Tonnes Per Annum
TWA	Time Weighted Average
VOC	Volatile Organic Carbons
vPvB	Very Persistent very Bioaccumulative
ZDDP	Zinc Dialkyldithiophosphate

ANNEX 1

Department for Environment, Food and Rural Affairs

Environmental risk reduction strategy and analysis of advantages and drawbacks for medium chain chlorinated paraffins (MCCPs)

Updated report

November 2008

Entec UK Limited

Department for Environment, Food and Rural Affairs

Environmental risk reduction strategy and analysis of advantages and drawbacks for medium chain chlorinated paraffins (MCCPs)

Updated report

November 2008

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Document Revisions

No.	Details	Date
1	Report for UK risk reduction strategy steering group (reference 12667CA068)	04/12/2004
2	Updated (draft) report to take into account updated risk assessment and comments on previous report	20/02/2008
3	Updated (draft) report to provide information for preparation of Annex XV dossier	24/11/2008

The following document's page numbers re-start to link into the contents page for the risk reduction strategy.

Executive Summary

Background

A European Union risk assessment has identified a need to limit the risks to the environment associated with the use of medium chain chlorinated paraffins (MCCPs) in a number of applications, including use in PVC compounding and conversion; use in compounding and conversion of rubber and polymers other than PVC; formulation and use of metal cutting/working fluids; use in leather fat liquors; recycling of carbonless copy paper; and waste remaining in the environment. A concern has also been raised regarding the potential persistence, bioaccumulation and toxicity (PBT) properties of MCCPs.

Based on the results of the risk assessment, the UK was required to recommend a strategy for limiting the risks to the environment. The Department for Environment, Food and Rural Affairs (Defra) has contracted Entec UK Limited to develop this strategy.

This report presents the results of the risk reduction strategy, taking into account the valuable input from the steering group for the project, comments from consultees and discussions/comments from risk reduction strategy meetings led by the European Commission. This document is an update of previous draft reports (of December 2004 and February 2008), reflecting significant changes that have been made to the risk assessment conclusions and comments received from various parties.

The objective of this work was to assess the advantages and drawbacks of different risk reduction options, primarily for the environment, on the use of MCCPs to:

- enable judgement as to whether the benefits of adopting the restrictions outweigh the consequences to society as a whole of imposing the controls; and
- determine the best risk reduction strategy offering the greatest net benefits.

The report includes the results of a semi-quantitative assessment of the advantages and drawbacks of possible risk reduction options. Conclusions are drawn on what is considered to represent the most appropriate risk reduction strategy for each sector and overall.

Consultation with relevant stakeholders has taken place and a number of possible options for addressing the risks have been evaluated. These options include limiting/reducing emissions to the environment through legislation or a voluntary agreement; and restricting certain uses of MCCPs either through legislation or through a voluntary commitment. A range of existing measures that are in place and control the risks at certain sites and under certain legislative regimes have also been taken into account.

This report includes a systematic consideration of the likely impacts of the possible measures in terms of their effectiveness, practicality, economic impact and monitorability. Where practicable, quantified information has been provided on the levels of reduction in risk that could be achieved by, and the technical/economic implications of, the risk reduction options. This has been based on information provided through consultation with stakeholders, estimates from the literature and estimates developed by Entec.

It is considered that the quantitative data, supplemented with qualitative information on the likely impacts of the possible measures for each sector, provides a suitable basis for understanding the likely consequences of implementing those measures and for determining the most appropriate strategy for each sector.

Based on the analysis undertaken, it is concluded that there is no single measure that could be introduced to limit the risks associated with MCCPs and which would at the same time not pose significant drawbacks in terms of cost, technical efficacy or potential risks from substitutes. Therefore, it is concluded that a combination of measures is required.

As the risk reduction strategy for MCCPs has not been finalised under Regulation 793/93, an Annex XV dossier will be produced by the Health and Safety Executive (HSE) to take forward the conclusions reached for MCCPs and recommended restrictions under REACH.

A number of organisations have provided additional information and/or comments following production of the February 2008 version of the risk reduction strategy report. The purpose of this report is to provide Defra with a final version of the environmental risk reduction strategy, taking into account the views of other Member States and the additional information made available. This will allow Defra to provide HSE with relevant information from the environment risk reduction strategy in order to inform production of the Annex XV dossier.

Overview of approach to drawing conclusions

Conclusions on appropriate measures based on the risk assessment

As indicated above, each of the possible risk reduction options has been assessed taking into account the effectiveness, practicality, economic impact and monitorability of the options for each of the uses of MCCPs for which the need to reduce the risk was identified taking into account existing measures.

The risk reduction strategy has been developed based on the conclusions of the risk assessment (primarily the PEC/PNEC ratios) and the existing measures that are understood to be applied within each of the sectors.

The majority of the conclusions in the risk reduction strategy (draft of February 2008) were agreed at the 15th risk reduction strategy meeting.

However, at this meeting, several Member States indicated that they foresaw a need for further (precautionary) restrictions on marketing and use of MCCPs than was concluded to be appropriate in the risk reduction strategy based on the PEC/PNEC ratios approach. This was on the basis of current uncertainties regarding the PBT status of MCCPs. This has been taken into account in the following sections.

Consideration of restrictions on marketing and use

Where marketing and use restrictions have been considered, a range of factors have been taken into account, including:

- Firstly, whether the risks could be controlled through other measures that would impose less significant economic implications on EU industry;
- Whether there are available alternatives to use of MCCPs;
- Information available on the hazards and risks of those alternatives, including the associated uncertainties;
- The technical suitability of potential alternatives for the various uses of MCCPs;
- The economic implications of replacing MCCPs with alternatives.

Whilst the approach to determining whether restrictions are appropriate for any given use of MCCPs has been as objective and systematic as possible in practical terms, it is inevitable that there will be some degree of judgement involved in drawing overall conclusions.

This is particularly true with regard to the potential PBT properties of MCCPs and the recommendation in the risk assessment that consideration be given to possible precautionary action given the current uncertainties on this aspect. The analysis below takes into account the views of several Member States that further restrictions may be warranted on the basis of possible PBT properties (this is included in a separate section).

Measures to address quantifiable risks

Overview

Quantifiable risks in this context relates to risks identified in the risk assessment based on the PEC/PNEC ratios calculated for each environmental compartment and each use of MCCPs.

It is concluded that there is no single measure that could be introduced to limit the risks associated with MCCPs and which would at the same time not pose significant drawbacks in terms of cost, technical efficacy or potential risks from substitutes. Therefore, it is concluded that a combination of measures is required.

In particular, controls under the Water Framework Directive and IPPC Directive could target a number of different uses and releases to the environment. These are considered as over-arching or cross-cutting measures. Following implementation of such measures, a number of additional measures are identified that are concluded to be suitable to address the residual risks.

Cross-cutting measures

Water Framework Directive

In order to address emissions to the environment from the range of installations, it is considered appropriate for the European Commission to consider the inclusion of MCCPs in the priority list of Annex X to Directive 2000/60/EC during the next review of this Annex.

It is concluded that this measure could address a significant proportion of the identified risks (excluding those where additional specific measures are suggested below). In addition to addressing the risks to surface water, sediment and secondary poisoning via the fish-based food chain, achieving compliance with an EQS under the Water Framework Directive could substantially target risks to the terrestrial compartment and secondary poisoning via the earthworm-based food chain provided that emissions are reduced at source (as set out in Section 5.4.1 of this report).

It is recognised that the success of this measure is dependent upon the enforcement within the Member States and also that it will take some time until controls will be required to be in place. However, given the relative scale of the PEC/PNEC ratios (except where additional measures are proposed below to control the highest concentrations), it is considered that this approach is proportionate to the level of risk identified.

Following the 15th risk reduction strategy meeting, based on the results of the risk reduction strategy, the following measures were included in a draft recommendation on MCCPs (European Commission, 2008):

- *To consider the inclusion of MCCPs in the priority list of Annex X to Directive 2000/60/EC during the next review of this Annex.*
- *It is recommended that for river basins where emissions of MCCPs may cause a risk, the relevant Member State(s) establish EQSs and the national pollution reduction measures to achieve those EQS in 2015 shall be included in the river basin management plans in line with the provisions of Directive 2000/60/EC .*
- *Local emissions to the environment of MCCPs should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.*

IPPC Directive

In order to ensure that emissions from the largest installations in key sectors (PVC, metalworking, rubber/other polymers), it is considered appropriate for the conclusions of the risk assessment and this risk reduction strategy to be taken into account in ensuring that emissions from these installations do not cause environmental concentrations in excess of the PNEC value.

Following the 15th risk reduction strategy meeting, based on the results of the risk reduction strategy, the following measures were included in a draft recommendation on MCCPs (European Commission, 2008):

- *Competent authorities in the Member States concerned should lay down, in the permits issued under Directive 2008/1/EC of the European Parliament and of the Council , conditions, emission limit values or equivalent parameters or technical measures regarding MCCPs in order for the installations concerned to operate according to the best available techniques (hereinafter "BAT") taking into account the technical characteristic[s] of the installations concerned, their geographical location and the local environmental conditions.*
- *To facilitate permitting and monitoring under Directive 2008/1/EC MCCPs should be included in the ongoing work to develop guidance on 'Best Available Techniques'.*

Leather fat liquors

It is concluded that restricting the marketing and use of MCCPs is the most appropriate option for use in leather fat liquors. This is on the basis that the other possible measures considered could not be relied upon to effectively reduce the risks in a practical manner and because the economic impact of this measure is expected to be less significant than for other sectors. There are also understood to be widely used substitutes that are likely to pose lower risks for the environment.

Other measures, such as control under the IPPC Directive or voluntary agreements, are not considered to be sufficiently reliable alone to address the identified risks.

Metalworking fluids

Emulsifiable metalworking fluids

The identified risk relates to intermittent releases of large quantities of MCCPs in emulsifiable metalworking fluids.

For use in emulsifiable metalworking fluids, it is concluded that the most appropriate option is to ensure that legislation is in place to prevent the intermittent release of large quantities of fluids containing MCCPs (e.g. though ensuring that such wastes are properly disposed of).

Whilst existing legislation (such as the Waste Oils Directive, 75/439/EEC) effectively includes a requirement that should prevent releases such as this, this practice cannot be ruled out; it has been acknowledged that the Directive has not been well implemented and that waste oil collection rates remain too low. The new Directive on Waste appears to provide a means by which Member States would be required to ensure that risks to the environment are addressed (see Section 3.8).

If this measure is successful in addressing the intermittent release scenario, there will no longer be a concern for use in emulsifiable metalworking fluids and so wider restrictions on use of MCCPs in this application are not considered to be the most appropriate risk reduction option on the basis of the PEC/PNEC ratios approach.

Oil-based metalworking fluids

For oil-based metalworking fluids, the most appropriate means of control is considered to be through the IPPC Directive (this will only cover certain larger installations) and the Water Framework Directive, as described above.

Given the available information on alternatives to MCCPs, it is concluded that restrictions on the marketing and use of MCCPs in this application is not the most appropriate option at the current time based on the PEC/PNEC ratios approach to assessment of the risks. This is because:

- Whilst use of alternative metalworking fluids or alternative production techniques has been shown to be possible in certain applications, evidence from a wide range of sources suggests that substitution in certain extreme pressure applications is not technically feasible while preserving the desired properties of the end product. It has not been possible to draw up a comprehensive list of applications where this is the case but those identified as potentially falling into this category include deep drawing; punching; extrusion; pilgering; forming; drilling; tapping; rimming; threading; boring; and broaching.
- Whilst there is a wide range of potential alternatives to MCCPs that may be used for certain applications, the available information suggests that these may have properties that could pose significant risks to health and/or the environment.

If any future decision is taken to restrict use of MCCPs, these considerations should be taken into account.

Use in PVC

Overall conclusion

For use of MCCPs in PVC, it is considered that the approach representing the most appropriate balance of advantages and drawbacks would be to ensure that emissions are controlled to an adequate level through inclusion of MCCPs as a priority substance under the Water Framework Directive (with subsequent measures to set and achieve an EQS) and control of emissions from those (larger) installations covered by the IPPC Directive in accordance with the conclusions of the risk assessment.

These measures could be expected to significantly reduce emissions of MCCPs below the levels identified in the risk assessment. The costs of implementing these measures for operators are estimated to be significantly less than for replacement under marketing and use restrictions. Moreover, this approach would not (directly) introduce additional risks associated with the use of substitutes, several of which are also have concerns in relation to environmental impacts.

However, this does not take into account the implications for environmental risks if MCCPs are determined to have PBT properties and this is considered in more detail in Section 6.4.

Uses where only a plasticising effect is required

In applications where MCCPs are used primarily for their plasticising properties, there are available alternatives that could be used which appear to pose lower risks for the environment (e.g. DINP). Such alternatives will generally be considerably more expensive than MCCPs.

However, the economic impact of substitution is not the only factor that needs to be taken into account in determining the most appropriate risk reduction strategy. Information collated for this risk reduction strategy suggests that it is possible to control releases of MCCPs to the environment to a level where it could reasonably be expected that there would no longer be a need for limiting the risks (i.e. PEC/PNEC ratio <1; given that the realistic worst case assessment suggests that PEC/PNEC ratios are relatively low compared to some uses); as practices vary amongst sites. It is concluded that, if measures are taken to ensure that this achieved through the Water Framework Directive, for example, these risks could be addressed in a more proportionate manner.

Uses where flame retardancy is required

In relation to control of the identified risks, the same conclusions as apply to uses where MCCPs are used primarily for their plasticising effects also apply to uses where they are used for their flame retardant properties.

However, with regard to the implications of possible replacement of MCCPs, the available information suggests that the drawbacks of a possible restriction would be more significant for these uses. In particular:

- The economic implications of substitution would be expected to be significantly greater, due to the types of substances that would be required in order to achieve the same degree of flame retardancy.
- Whilst the available information on alternatives to MCCPs is less complete than that for MCCPs themselves, the information that is available suggests that identified alternatives may not lead to a significant reduction in risks (e.g. preliminary PEC/PNEC ratios aryl phosphates are in several cases much higher than for MCCPs).

Losses during the service life of products

Whilst the risk assessment does not identify a specific need for limiting the risks associated with losses of MCCPs from PVC products during their service life, such releases may potentially be significant. This issue is potentially important in the context of the possible PBT properties of MCCPs, as described below.

Rubber and polymers other than PVC

Given that the total emissions from this sector are low, the highest PEC/PNEC ratio identified is only 1.23 and the potentially high costs of substituting MCCPs, it is concluded that the most appropriate controls for this use are for appropriate emission limit values to be introduced (where this is not already the case) under the IPPC regime and for controls to be introduced on discharges, emissions and losses through recommendation that MCCPs be included on the priority list of substances under the Water Framework Directive (see above).

As with PVC, there is the potential for quite significant releases from these products during their service life. Whilst the risk assessment does not identify a specific need for limiting the risks associated with losses of MCCPs from rubber/other polymer products during their service life, such releases may potentially be significant. This issue is potentially important in the context of the possible PBT properties of MCCPs, as described below.

Carbonless copy paper

Given that the highest PEC/PNEC ratio for this use is 1.1 and that the latest information suggests that use no longer occurs in this application, it is concluded that no further measures would be required at the current time to address the risks associated with this use.

In the event that MCCPs begin to be used in this application in the future, measures under the Water Framework Directive and the IPPC Directive, if adopted to target other uses, should be sufficient to address any remaining risks associated with this use.
It may be appropriate to confirm compliance with (or even give formal recognition to) the industry agreement not to use MCCPs in order to avoid future use of MCCPs in this application.

Other uses

For the other uses of MCCPs, including production of MCCPs, no need for limiting the risks is identified in the latest version of the risk assessment. For 'waste remaining in the environment' it is concluded that there is insufficient certainty with regard to the risk assessment conclusions to draw firm conclusions on the most appropriate risk reduction measures.

Therefore, no additional measures are considered appropriate for these uses based on the risks identified using the PEC/PNEC approach.

Summary of conclusions on most appropriate measures

The table below provides a summary of the measures that it has been concluded represent the best balance of advantages and drawbacks for each of the relevant sectors in relation to the identified risks.

Summary of conclusions on most appropriate measures

Use	M&U	IPPC	WFD	Waste oils
Metalworking		✓	✓	✓
Leather	✓			
PVC		✓	✓	
Rubber / other polymers			✓	
Carbonless copy paper [1]		✓	✓	
Other uses		✓	✓	

[1] It may also be appropriate to verify compliance with (or even give formal recognition to) the AEMCP industry agreement not to use MCCPs. Note that use no longer occurs in this application.

Possible further restrictions

The above discussion relates to measures that are concluded to be appropriate to address the environmental risks associated with MCCPs based on the uses for which a need for limiting the risks has been identified using the PEC/PNEC ratios approach. It is considered that the measures identified above represent the best balance of advantages and drawbacks for society as a whole, taking into account the level of risk identified based on those PEC/PNEC ratios.

However, the updated version of the risk assessment also concludes that consideration may need to be given to precautionary action to address the possible PBT properties of MCCPs, including the implications of 'waste remaining in the environment'. In particular, it was not possible to say on a scientific basis whether there is a current or future risk to the environment related to the possible PBT properties of MCCPs.

The need for possible precautionary action was identified because of: data indicating presence in marine biota; the apparent persistence of the substance; the time it would take to gather information to confirm whether MCCPs fulfil the PBT criteria; and the fact that it could be difficult to reduce exposure if the additional information confirmed a risk.

The majority of the risk reduction strategy was agreed at the 15th risk reduction strategy meeting (as incorporated into the draft recommendation on MCCPs to be handed over to ECHA, ES/12f/2007 Rev. 1).

However, the extent of the proposed restrictions on use (limited to use in leather fat liquors, as described above) was questioned with several Member States indicating a need for precautionary action to be taken given the current uncertainties regarding the

PBT status of MCCPs and suggesting that further restrictions would be appropriate, particularly for metalworking fluids and PVC[9].

This document is intended to reflect the outcome of an objective and impartial analysis of available options to address the risks associated with MCCPs. It is not considered appropriate to provide advice for or against any possible precautionary action to restrict the use of MCCPs within this document as any decision to take precautionary action should be based on a political judgement[10]. Appendix E provides information from the February 2008 draft of this risk reduction strategy (presented at the 15th risk reduction strategy meeting) regarding factors that may be taken into account in any such precautionary decision.

The assertion by several Member States that restrictions on other uses would be warranted on a precautionary basis should be taken into account at a political level in determining what restrictions, if any, are taken forward for MCCPs.

Work on determining the potential PBT properties of MCCPs is still underway and is not expected to be complete before 2009.

If MCCPs are determined to have PBT properties, it may be concluded that MCCPs would be a suitable candidate for inclusion on Annex XIV under REACH (i.e. substances subject to Authorisation). According to Article 58(3) of the REACH Regulation, in making any decision to include substances on Annex XIV, priority shall normally be given to substances with:

(a) PBT or vPvB properties; or
(b) wide dispersive use; or
(c) high volumes.

If MCCPs are determined to have PBT properties, they could be concluded to fulfil all of these criteria. They may be concluded to have a wide dispersive use, particularly given that MCCPs are used at many sites (e.g. metalworking uses) and that the risk assessment concludes that releases during service life may be significant. They are also used in high volumes, nearly 64,000 tonnes in the EU in 2006.

Taking into account the outcome of the ongoing testing on possible PBT properties of MCCPs, ECHA may wish to consider whether it would be appropriate to include MCCPs on Annex XIV of the REACH Regulation.

Recommendations

The information available for preparation of this report is considered to provide a suitable basis for determining which measures are likely to be most appropriate for each

[9] Draft summary record of the 15th Risk reduction strategy meeting of the Member States for the implementation of Council Regulation (EEC) 793/93 on the evaluation and control of risks of existing substances, 22-24 April 2008, (Doc. ES/05/2008).
[10] See for example, Communication from the Commission on the precautionary principle, COM(2000)1 final, Brussels, 2.2.2000.

sector (although the level of information available differs significantly amongst the sectors) based on the risks identified using PEC/PNEC ratios. The measures identified are considered sufficient to address the risks identified on that basis though they will not necessarily address the risks identified on the basis of the *possible* PBT properties of MCCPs.

The elements of this risk reduction strategy that do not relate to restrictions were agreed at the 15th risk reduction strategy meeting. Furthermore, it was concluded that restrictions on the marketing and use of MCCPs in leather were the most appropriate risk reduction option for this use. It is recommended that the UK Government takes the findings of this report into account in the Annex XV dossier being prepared for MCCPs under REACH.

With regard to any possible further controls on MCCPs, it is recommended that the findings of this report, along with the results of the ongoing testing to determine PBT properties and the views of Member States expressed at the 15th risk reduction strategy meeting, be taken into account in determining the most appropriate means of addressing the risks.

It is also recommended that consideration be given by industry to the acceptability and practicability of the identified measures where the most appropriate option involves possible negotiated/voluntary action to reduce the risks.

Contents

BACKGROUND

Overview

Basis for contract

Under Regulation 793/93/EEC, medium chain chlorinated paraffins (MCCPs) were identified as a priority substance in relation to their potential effects on humans and the environment. The UK is the designated *rapporteur* for MCCPs and is responsible for evaluation of the risks posed to health and the environment and, where appropriate, for suggesting a strategy for limiting the risks.

Responsibility for carrying out the environmental risk assessment rests with the Environment Agency and the worker protection and human health assessment with the Health and Safety Executive.

A need for limiting the environmental risks associated with various uses of MCCPs has been identified through the risk assessment. On the basis of this assessment, the Department for Environment, Food and Rural Affairs (Defra) has contracted Entec UK Limited to develop a strategy for limiting the environmental risks.

The objective of the work was to assess the advantages and drawbacks of different risk reduction options, primarily for the environment, on the use of MCCPs to:

- enable judgement as to whether the benefits of adopting the restrictions outweigh the consequences to society as a whole of imposing the controls; and
- determine the best risk reduction strategy offering the greatest net benefits.

Under the Existing Substances Regulation, the risk reduction strategy for MCCPs was not finalised. Therefore, information is needed under REACH for submission of an Annex XV dossier on this substance as a 'transitional' substance.

This work has been carried out under a framework contract between Defra and Entec (CPEC24).

Need for a risk reduction strategy

The results of the risk assessment are described in Section 2 of this report. In summary, a need for limiting the risks to the environment has been identified for the following stages in the lifecycle of MCCPs:

- Use in PVC compounding and conversion;
- Use in conversion of rubber and polymers other than PVC;
- Formulation and use of metal cutting/working fluids;
- Use in leather fat liquors;

- Recycling of carbonless copy paper; and
- 'Waste remaining in the environment'.

These identified risks relate to surface water, sediment, the terrestrial environment and secondary poisoning[11]. A risk is also identified in relation to 'waste remaining in the environment'.

As described in the environmental risk assessment (ECB, 2005), it is considered that MCCPs are very toxic to aquatic organisms and that they may cause long-term adverse effects in the aquatic environment.

Approach to development of the strategy

The basis for development of this risk reduction is the environmental risk assessment (ECB, 2005).

Table 1.1 summarises the key stages to be undertaken in development of the risk reduction strategy, as specified by Defra. In development of the risk reduction strategy, the approach taken is in accordance with the EU Technical Guidance Document on Development of Risk Reduction Strategies (European Commission, 1998).

Table 1.1 Main stages in development of the risk reduction strategy

Stage	Work undertaken
Stage 1	Data gathering and evaluation of all known uses of MCCPs. Determination of control measures currently in place and establishment of a range of potential risk reduction options.
Stage 2	A systematic qualitative assessment of the advantages and drawbacks for each of the options identified. Recommendations as to the need for a (semi) quantified approach.
Stage 3	A semi-quantified or fully quantified assessment of one or more risk reduction options for the uses of concern.
Stage 4	Preparation of the final risk reduction strategy.
Stage 5	Preparation of a Regulatory Impact Assessment (RIA) for the UK.

This report represents Stage 4 of the risk reduction strategy, incorporating the results of the preceding stages and taking into account the valuable input from the steering group for the project. It includes the results of the semi-quantitative assessment of the advantages and drawbacks of possible risk reduction options and takes into account comments of the steering group on these results. Conclusions are drawn on what is considered to represent the most appropriate risk reduction strategy for each sector and overall. The approach taken in preparation of this report involved:

- A review of relevant literature;

[11] Secondary poisoning relates to effects in the higher members of the food chain, either living in the aquatic or terrestrial environment, which result from ingestion of organisms from lower trophic levels that contain accumulated substances.

- Consultation with a range of industry associations and companies on the implications of the potential risk reduction measures;
- Consideration of the potential environmental benefits through reducing or eliminating emissions of MCCPs, based on the likely impacts of the potential measures;
- Examination of the financial and technical implications that the potential measures would have for companies involved in production and use of MCCPs. This has been based on consultation with relevant industry stakeholders (see Appendix A), as well as literature on relevant techniques; and
- Consideration of the implications of substitution of MCCPs in the various applications, based on various literature sources and consultation.

A detailed sector-by-sector discussion of the implications of possible risk reduction measures is included in Appendix B to this report.

This version of the report

The original Stage 4 report setting out the risk reduction strategy was produced in 2004. Given that various additional analyses were to be undertaken for the risk assessment (environment and human health), it was recognised that the risk reduction strategy report should be considered provisional. As such, a presentation was made at the March 2005 risk reduction working group meeting based on what was currently being considered in the strategy given the risk assessment conclusions at the time. Following the 2004 version of the report, additional testing was undertaken and revisions have been made to the risk assessment in the form of an addendum (though the PBT assessment is not yet finalised). The revised risk assessment indicated significant changes to the conclusions, particularly on secondary poisoning (with a need for limiting the risks now identified for only one use in relation to the fish-based food chain and with much reduced risks identified for the earthworm-based food chain). The risk reduction strategy report was therefore updated and discussed at the 15th and final risk reduction strategy meeting in April 2008.

The majority of the risk reduction strategy was agreed at the 15th risk reduction strategy meeting (as incorporated into the draft recommendation on MCCPs handed over to ECHA, ES/12f/2007 Rev. 1).

However, the extent of the proposed restrictions on use (limited to use in leather in the risk reduction strategy) was questioned with several Member States indicating a need for precautionary action to be taken given the current uncertainties regarding the PBT status of MCCPs and suggesting that further restrictions would be appropriate, particularly for metalworking fluids and PVC[12]. The February 2008 risk reduction strategy report did not conclude that wider restrictions were the most appropriate risk

[12] Draft summary record of the 15th Risk reduction strategy meeting of the Member States for the implementation of Council Regulation (EEC) 793/93 on the evaluation and control of risks of existing substances, 22-24 April 2008, (Doc. ES/05/2008).

reduction measure (unless MCCPs are found to be PBT) based on the balance of advantages and drawbacks for the other sectors and the potential to control emissions. Following the risk reduction strategy meeting, additional information was requested by Defra from attendees to support the suggestions that were made regarding wider restrictions.

The human health risk assessment has identified a need to limit the risks for oil-based metalworking fluids. The human health strategy was not discussed by the risk reduction strategy working group. MCCPs were not finalised under the Existing Substances Regulation and are a transitional substance under REACH.

Transitional arrangements will be under REACH Regulation Article 136(3) as set out in the DG Environment document on Handover of the Workplan risk reduction strategies 2006-2008 (dated 18 July 2008, doc: ES/03/2005 final, Rev.11).

As the risk reduction strategy for MCCPs has not been finalised under Regulation 793/93, an Annex XV dossier will be produced by the Health and Safety Executive (HSE) to take forward the conclusions reached for MCCPs and recommended restrictions.

A number of organisations have provided additional information and/or comments following production of the February 2008 version of the risk reduction strategy report. The purpose of this report is to provide Defra with a final version of the environmental risk reduction strategy, taking into account the views of other Member States and the additional information made available. This will allow Defra to provide HSE with relevant information from the environment risk reduction strategy in order to inform production of the Annex XV dossier.

Note that the consultation and literature review for the risk reduction strategy were mainly undertaken during 2004. Some additional literature has been taken into account, along with additional inputs from consultees (including other Member States), in this revised risk reduction strategy. ***We would like to thank all organisations that provided information for this risk reduction strategy for their contributions.*** ***A list of the organisations consulted is provided in Appendix A.***

Use pattern of MCCPs

What are MCCPs?

Chlorinated paraffins have been produced commercially for over 50 years. They are based on normal paraffin fractions produced in the petroleum industry and are produced by the addition of chlorine gas in a stirred reactor (Houghton, 2003) to the required degree of chlorination. In general, three groups of chlorinated paraffins are produced commercially. These are usually mixtures of different chain length with differing degrees of chlorination and are as follows:

- Short-chain chlorinated paraffins, SCCPs (C_{10-13});

- Medium-chain chlorinated paraffins, MCCPs (C_{14-17}); and
- Long-chain chlorinated paraffins, LCCPs ($\geq C_{18}$ or C_{20-30}).

This report is concerned only with MCCPs (those having a carbon chain length C_{14-17}). SCCPs have already been assessed under the Existing Substances Regulation. LCCPs are not included as a priority substance under this Regulation, but are currently undergoing risk assessment in the UK, as well as a hazard assessment under the ICCA HPV initiative[13].

MCCPs are produced commercially with between 40% and 70% chlorine by weight; however, the majority of the tonnage of MCCPs on the market has between 45% and 52% chlorine by weight.

A range of different CAS Numbers are – or have been – used to describe commercially produced chlorinated paraffins. These are summarised in Table 1.2. It can be seen that several different CAS numbers include substances that may have carbon chain length C_{14-17}.

13 International Council of Chemical Associations - High Production Volume Chemicals Initiative (see http://www.iccahpv.com).

Table 1.2 CAS numbers used for chlorinated paraffins

CAS No	Definition	CAS No	Definition
61788-76-9	* alkanes, chloro; alkanes, chlorinated	85535-85-9	* alkanes, C14-17, chloro
63449-39-8	* paraffin waxes and hydrocarbon waxes, chloro	85535-86-0	alkanes, C18-28, chloro
68920-70-7	alkanes, C6-18, chloro	85536-22-7	alkanes, C12-14, chloro
71011-12-6	alkanes, C12-13, chloro	85681-73-8	alkanes, C10-14, chloro
84082-38-2	alkanes, C10-21, chloro	97553-43-0	paraffins (petroleum), normal C>10, chloro
84776-06-7	alkanes, C10-32, chloro	97659-46-6	alkanes, C10-26, chloro
84776-07-8	alkanes, C16-27, chloro	106232-85-3	alkanes, C18-20, chloro
85049-26-9	alkanes, C16-35, chloro	106232-86-4	alkanes, C22-40, chloro
85422-92-0	* paraffin oils and hydrocarbon oils, chloro	108171-26-2	alkanes, C10-12, chloro
85535-84-8	* alkanes, C10-13, chloro	108171-27-3	alkanes, C22-26, chloro

Source: Ineos Chlor (2004)

* = Most commonly used by industry because they meet the needs of various inventories around the world, including EU, USA, Canada, Australia, Korea, Japan, Philippines and China.

Summary of uses

In 2004, there were six sites manufacturing MCCPs in the EU. Table 1.3 provides a summary of the applications for MCCPs at the EU level, based on information from the environmental risk assessment data provided by *Eurochlor*, the trade association representing suppliers of MCCPs to the EU market.

Table 1.3 Summary of MCCP use in the EU (metric tonnes)

Application	EU 1994 [1]	EU 1997 [1]	EU 2003 [2]	EU 2006 [3]
Polyvinyl chloride (PVC)	45,476	51,827	32,450	34,676
Metal working/cutting	2,611	5,953	8,113	9,907
Paints, adhesives and sealants	3,079	3,541	8,236	11,323
Rubber/polymers (other than PVC)	2,497	2,146	3,521	7,077
Leather fat liquors	1,614	1,048	1,411	708
Carbonless copy paper	1,296	741	89	-
Total	**56,573**	**65,256**	**53,820**	**63,691**

[1] ECB (2005). [2] Cefic (2004). Data for 2003 included 2,894t 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] Eurochlor (2008a). 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.

Data on use in the EU for 1997 were used in the environmental risk assessment (ECB, 2005). As can be seen from Table 1.3, the use of MCCPs in PVC has fallen significantly since 1997, whilst use in metalworking/cutting fluids has increased over the same period. It is expected that the increase in this application has resulted from substitution of short-chain chlorinated paraffins (C_{10-13}) with MCCPs, as a result of impending – and now implemented – legislation restricting marketing and use in these applications[14]. (When legislation on SCCPs was being considered, many users indicated that they would use MCCPs as replacements for SCCPs in the event of restrictions.)

The environment risk assessment (ECB, 2005) gives consideration to the substitution of SCCPs with MCCPs and the impact of this upon risks to the environment. This is considered further in Section 2.

Information has been made available on use in a number of Member States, as illustrated in Table 1.4.

[14] Under Directive 2002/45/EC (and now under REACH), short-chain chlorinated paraffins may not be placed on the market for use in concentrations higher than 1% in either metalworking or fat liquoring of leather. This restriction was introduced based on the risks posed to the environment.

Table 1.4 Use of MCCPs in some EU Member States and Norway (metric tonnes)

Application	Germany & Austria (2006) [1]	Sweden (2005) [2]	Norway (2005) [3]	UK (2003) [4] (approximate)
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**

[1] Eurochlor (2008). The data listed as “rubber/polymers” are referred to as “flame retardant textiles and rubber” in the source data. [2] Kemi (2008). Note that the 3.5t indicated as used in PVC is cited as used in “plastics” in the reference. [3] NCPA (2007). [4] MCCP User Forum 2003 (sales data, extrapolated from data up to September 2003).

Price of MCCPs

Based on the quantity sold in 2003, it is estimated that the annual market for MCCPs in the EU is worth around £19 million (€28 million) per year. The corresponding figure for 2006 is around €32 million per year. This is based on a price of chlorinated paraffins quoted in the literature of around $US0.32/kg (Houghton, 2003), with the actual value expected to be around twice this value, on average, or just over €500 per tonne. [15].

The price of MCCPs is considered to be confidential by the EU producers. However, information from a company using MCCPs in PVC products suggests a price of £420 per tonne (around €625 per tonne), although the historic price was generally lower than this since larger quantities were previously purchased. However, the price of MCCPs will vary in practice – as it will for any chemical – due to a number of factors, including:

- Quantities purchased;
- Variability in raw material and other input costs;
- Grades of MCCPs sold into particular applications;
- Customer relationships and other commercial factors, such as national and international competition.

For the purposes of this risk reduction strategy a price for MCCPs of €500 per tonne has been assumed. Whilst it is recognised that prices do vary significantly – both for MCCPs and for potential alternatives – a single value is used here because detailed

[15] Exchange rates of £0.54/$US and £0.67/€ were used based on data in 2004 from: http://www.marketprices.ft.com/markets/currencies/ab.

information is not available on price variability and in order to provide a consistent basis for comparison.

Based on discussions with producers and users of MCCPs, it is understood that there are no uses of MCCPs that would fall outside the use categories considered in the environmental risk assessment and listed in Table 1.3. Therefore, it is considered that there is no need to extend the scope of the analysis to other possible uses.

Use in PVC

MCCPs are frequently employed in PVC formulations as secondary plasticisers with flame-retardant properties. They may act as partial replacements for the more expensive primary plasticisers such as phthalates (di-isononyl phthalate and di-isodecyl phthalate, for example) and phosphate esters. In addition to their cost-effectiveness, properties of PVC such as fire retardancy, chemical and water resistance, low temperature performance and viscosity stability may all be enhanced through incorporation of MCCPs.

According to industry[16], MCCPs can be used in a wider variety of PVC formulations and in combination with a broader range of other plasticisers than any other plasticiser type. PVC containing MCCPs can be recycled, with the MCCP kept in the PVC matrix for multiple product lifecycles[17].

Typical applications for PVC products containing MCCPs include cables, flooring, wallcoverings and general extruded and injection moulded articles (CSF, 2002[18]). It is estimated that around 16.7% is used in cables, 33.3% in each of flooring and wallcoverings and 16.7% in other uses[19].

In 1999, over 800,000 tonnes of PVC flooring was sold and around 760,000 tonnes of PVC compounds for cables are produced each year in Western Europe. Total Western European production of PVC is around 5.5 million tonnes (ECVM, 2004) and total sales in the enlarged European Union[20] were 6.85 million tonnes in 2003 (APME, 2004). Since MCCPs are typically used at 10-15 parts per hundred resin (phr), the total amount of PVC used with MCCPs is estimated to be 220,000 to 320,000 tonnes per year, or around 4-6% of total PVC produced in Western Europe. PVC flooring containing MCCPs represents 9-14% of total 800,000 tonnes of PVC flooring sales. PVC cable compounds containing MCCPs represent around 5-7% of sales.

[16] Personal communication, Eurochlor, 6 June 2008.
[17] In 2007, 149,500 tonnes of post-consumer PVC was recycled, with a target for 2010 of 200,000 tonnes.
[18] Data provided by industry to the Chemicals Stakeholder Forum.
[19] Based on information from the sole UK producer in a report to the Chemicals Stakeholder Forum (RPA, 2002). 25% of sales are for companies undertaking PVC ‘compounding’ and supplying processors of pre-compounded PVC. It is assumed that the quantity used is in the same proportions as direct sales of MCCPs to processors.
[20] Includes the EU-25 except for Greece and Slovakia and including Norway, Switzerland and Romania.

However, sales of MCCPs into PVC are generally declining. This is due in part to the substitution of one of the most widely used primary plasticisers, di 2-ethylhexyl phthalate (DEHP), with other plasticisers such as di-isononyl phthalate. This is partly driven by the classification of DEHP as a Category 2 reproductive toxin in 2001. MCCPs are less compatible as a secondary plasticiser with DINP than with DEHP and so they are now less favoured in PVC formulations (MCCP User Forum, 2003). The reduction in use of MCCPs is also understood to have resulted from regulatory pressure on MCCPs. Note that the increased use in PVC reported for 2006 as compared to 2003 in this application is believed to be due in part to the increased geographical coverage (to include the EU-25).

Use in metalworking/cutting fluids

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)[21]. 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).

Metalworking fluids remove deformation heat and friction heat arising during cutting and additionally flush away chips and preventing dusting.

As indicated above, metalworking fluids of the type based on MCCPs may be used either as a neat oil or mixed with water to form an emulsion. Various other additives are used and the concentrations of MCCPs varies considerably.

Information for one formulator of metalworking fluids sold onto the UK market has been made available in terms of the percentage of sales by volume for different pack sizes. These are outlined in Table 1.5. As can be seen from this table, the majority is sold in intermediate bulk containers and barrels and could thus be expected to be used by larger metalworking companies.

Table 1.5 Sales from a UK formulator of chlorinated metalworking fluids by pack size

Pack Size	Neat Oils	Water Miscible
IBCs/barrels [1]	91.3%	75.4%
25 litre drums	6.9%	23.1%
5 litre bottles/cans	1.8%	1.5%

21 It is understood that use in greases and gear oils has now been largely phased out.

[1] IBC = intermediate bulk container.

Whilst companies of all sizes are understood to use either neat or emulsifiable metalworking fluids (or both), machines at smaller companies generally have smaller sumps and hence require only small quantities of metalworking fluid (of the order of a few litres, typically diluted to form a 5% emulsion). Smaller companies will often undertake less arduous machining and hence will more often use water miscible fluids (this also helps to keep down costs). Large machines may have sumps of several hundred or even several thousand litres.

Use in paints

MCCPs are used in paints based on various resin types. They are generally retained within the paint over its lifetime and primarily have a plasticising effect, reducing cracking and detachment of paints with good colour retention as compared to some alternatives. Typical applications are chlorinated rubber-based paints used in aggressive marine and industrial applications and vinyl copolymer-based paints used on exterior masonry (Houghton, 2003). They are typically used at concentrations of 1-5%, but this may be as high as 25%.

In the environmental risk assessment, it was assumed that one third of the total amount of MCCPs used in paints, sealants and adhesives were used in paints. This represented around 2,600 tonnes of MCCPs. Assuming an average concentration of MCCPs in paints of 5%, the amount of paints produced using MCCPs can be estimated to be around 50,000 tonnes per year. Sales of all paints in the EU-15 plus Norway and Switzerland were 5.6 million tonnes in 2001, with a sales value of €16 billion (Cepe, 2001). The market for paints containing MCCPs could, therefore, represent around 1% of EU paint sales, with a sales value of around €140 million per year.

The paint, printing inks and artists' colours industry employs 125,000 people in the EU. There are around 2.5 million professional painters in the EU (Cepe, 2004).
Other applications for paints containing MCCPs include sealers and coatings for concrete; general purpose, primers and undercoats for structural steel; roof coatings; above-water line marine coatings; swimming pool paints; masonry paints; chemical resistant coatings; high humidity resistant coatings; security fencing paints; damp-proof paints; flame retardant coatings for wood and paper; and floor coatings (CSF, 2002).

Use in adhesives and sealants

MCCPs are used particularly in polysulphide, polyurethane, acrylic and butyl sealants for use in building and construction, including double and triple glazed windows. They are primarily used for their plasticising and flame retardant properties (Houghton, 2003).

Sales of adhesives and sealants in Europe are worth around €6 billion per year based on 2003 sales data. Spending on research and development in the industry is around 3.1% of sales or €190 million per year (FEICA, 2004).

Use in rubber and plastics (other than PVC)

MCCPs are used in rubber such as nitrile, natural and styrene-butadiene. They are also used in polyurethane, especially rigid foams and one-component foams (CSF, 2002). Their primary function relates to their flame retardant properties.

Members of BLIC, the European Association of the Rubber Industry include around 1,200 companies in the (enlarged) EU. These companies employ more than 300,000 people and are mainly small and medium-sized enterprises (SMEs). The annual turnover of these companies is over €35 billion. The companies use around 4,000 different raw materials, of which 90% are preparations of more than one substance (BLIC, 2004).

Use in leather fat liquors

Use of MCCPs in leather treatment is understood to have ceased in the UK, although MCCPs are used in other EU countries. Use of MCCPs as fat liquors offers an alternative to natural oils, and these liquors are used in the top end of the quality range to provide light-fastness, strong binding to the leather and a dry surface feel (MCCP User Forum, 2003). Around 30% of leather fat liquors formulated in the EU are used in European tanneries with the remaining 70% exported and used overseas. This compares to data from the risk assessment in which around 50% was exported to outside the EU in 1997.

Detailed sectoral information on the leather tanning sector is available from the COTANCE website. In the EU-15 in 2002, the leather sector employed around 51,000 people in nearly 2,500 companies. The annual turnover of the sector was €8.1 billion (Cotance, 2004a). In 2006, employment was just under 40,000 in around 2,600 companies, with a turnover of €7.6 billion (in the enlarged EU) (Cotance, 2008). Table 1.6 displays more detailed data for the sector in 2006.

Based on 2003 sales data, around 1,400 tonnes of MCCPs were estimated to be used in the EU each year; this had decreased to around 700 tonnes in 2006 (even taking into account coverage of the EU-25 compared to EU-15 for the 2003 data). Based on the risk assessment, around 12kg MCCP is used per tonne of 'wet blue' and thus the amount of leather produced using MCCPs is around 59,000 tonnes per year based on 2006 usage data. Around 206,000 m^2 of leather were produced in the EU-27 in 2006 (around 84% of which was in Italy), which equates to just under 600,000 tonnes, and thus MCCPs could be used in as much as 10% of leather produced each year based on 2006 data[22]. This is expected to be a significant reduction compared to historical usage.

Use in carbonless copy paper

MCCPs can be used as solvents in carbonless copy paper and are used because of their high solvency for the dyes used and because they are immiscible with water, have low volatility and odour and do not react with the dyes or the material in which the dye is encapsulated (Houghton, 2003).

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[22] Based on a density of leather of 950 kg/m^3 and an assumed thickness of 3mm.

In 1992, members of the Association of European Manufacturers of Carbonless Paper agreed to stop using chlorinated paraffins in the production of carbonless copy paper. Members of the AEMCP account for around 95% of carbonless copy paper used in the EU (Environment Agency, 2004).

It is understood that sales of MCCPs reported for this application in 2003 related to one company only. This company has reportedly ceased trading and this application is no longer believed to be relevant for the EU (sales for this use were reported as zero for 2006).

Table 1.6 Leather tanning sectoral data in 2006

	Employment	Companies	Turnover (€'000)	Production (000 m²)	
				Cattle/calf	Sheep/goat
Belgium	123	1	22,092		
Finland	147	12	19,678		
France	1,695	63	270,000	3,370	2,805
Germany	2,350	22	480,000	13,000	500
Greece					
Hungary	85	3	5,200	62	
Italy	28,735	2,296	5,260,161	140,214	33,493
Netherlands					
Portugal					
Slovenia	376	7	77,670	59	4,318
Spain	4,304	139	975,893	na	na
Sweden	430	4	76,100	2,200	50
UK	1400	25	220,000	4000	2250
Lithuania					
Bulgaria			199,000		
Total	**39645**	**2572**	**7,605,794**	**162,905**	**43416**

Source: COTANCE (2008). Production data do not include Spain.

RISK ASSESSMENT

Risk assessment reports

The risk assessment which forms the basis for this risk reduction strategy is set out in the following documents:

- The main environmental risk assessment, as published by the European Chemicals Bureau (2005);
- An addendum to the risk assessment taking into account new information on toxicity to mammals and uptake from soil by root crops (Environment Agency, 2007);
- Additional information produced for the purposes of preparation of the Annex XV dossier under REACH (Environment Agency, 2008).

Conclusions referred to in this section are based on the former, except where the latter two provide information that supersedes what was included in the main assessment.

Effects of MCCPs in the environment

Table 2.1 provides a summary of the key ecotoxicological endpoints used in the environmental risk assessment for derivation of the 'predicted no effect concentrations' (PNECs[23]) used in determining the need for limiting the risks.

Table 2.1 Ecotoxicological endpoints used in risk assessment (ECB, 2005)

Environmental compartment	Endpoint	PNEC
Surface water	NOEC [1] of 10 µg/l in 21-day *Daphnia magna* reproduction study.	1 µg/l using assessment factor of 10.
Sediment	NOEC of 50 mg/kg wet weight in oligochaetes and amphipods.	5 mg/kg wet weight using assessment factor of 10.
Terrestrial compartment	NOEC of 248 mg/kg wet weight for earthworm.	10.6 mg/kg wet weight using assessment factor of 10 and normalising results based on soil organic carbon content.
Secondary poisoning	NOAEL [2] of 300 mg/kg food in rats.	10 mg/kg food using assessment factor of 30 (relates to exposure via accumulation in food chains).

[1] No observed effect concentration. [2] No observed adverse effect level.

23 The risks are calculated based on a comparison between the concentration predicted to occur in each environmental compartment (predicted environmental concentration, PEC) and the concentration at which no adverse effects are predicted to occur (PNEC).

As indicated in the environmental risk assessment, the proposed revision to the classification of MCCPs in relation to environmental effects was as follows:

- N (dangerous for the environment); and
- R50/53 (very toxic for aquatic organisms, may cause long-term adverse effects in the aquatic environment).

This environmental classification has now been agreed and incorporated into the 30th adaptation to technical progress of Directive 67/548/EEC[24].

Environmental exposure assessment

Appendix D provides a summary of the routes by which MCCPs were estimated to enter the environment based on the environmental risk assessment (ECB, 2005) for each of the main uses of MCCPs. Emissions from sites and from diffuse sources have been calculated using a variety of methods, including:

- Measured emissions data provided by industry specifically for the purposes of the risk assessment;
- Calculated emissions based on the techniques set out in the Technical Guidance Document for Risk Assessment (European Commission, 2003a);
- Calculated emissions based on sector specific guidance set out in 'emission scenario documents' for sectors such as plastics additives and coating processes; and
- Calculated emissions based on use patterns specific to MCCPs in the uses in question.

Based on the emissions data, the risk assessment includes information on the calculation of predicted environmental concentrations (PECs) in each of the compartments of interest. These values are also included in Appendix B. The PEC values are calculated by taking into account various factors including:

- The environmental medium into which MCCPs are released, taking into account dilution in those compartments;
- Partitioning between environmental compartments and during treatment at wastewater treatment works;
- Biological and abiotic degradation in the environment; and
- Bioaccumulation in organisms from the environment and biomagnification within food chains.

Local PEC values for each of the applications of MCCPs also take into account the background 'regional' concentration for each compartment.

Appendix D also provides a summary of emissions of MCCPs to air and wastewater for each of the scenarios considered including regional and total EU emissions, based on

24 Commission Directive 2008/58/EC of 21 August 2008, OJ L 246, 15.9.2008, p. 1.

the realistic worst case assumptions used in the risk assessment. This is based on the latest estimates of releases (Environment Agency, 2008).

By comparing total use in each application with the release information in Appendix D, recycling of carbonless copy paper has the most stark contrast between MCCP use and emissions, with one of the lowest total quantities used (in the formulation of carbonless copy paper), its recycling produces the highest non-intermittent local emission level. Emissions on the regional and continental scale are also relatively high, being higher than all other applications where a relatively low quantity is used overall (less than 5,000 tonnes per year). However, due to the apparent elimination of use in this application in recent years, there is currently considered to be a lower level of concern than there was historically.

Releases from metal cutting and working show relatively high levels compared to the total use and particularly in emissions to wastewater from large or small sites where use of MCCPs in oil-based fluids takes place. Occasional releases to waste water of 25 kg per 'event' relating to the use of emulsifiable fluids suggest very high but intermittent one-off releases. On the regional and continental level, estimations show very high emissions to wastewater. In this case (intermittent release of emulsifiable metalworking fluids) also emissions are currently expected to be lower than they were historically due to improvements in separation of the oil and water phases before disposal (see below). Formulation of leather also produces relatively high air and waste water emissions compared to the total level of MCCP use. High levels of local emissions are found relating to the complete processing of raw hides and the formulation of leather. Regional and continental data show that, although leather is a low user of MCCPs in terms of total volume, emissions on regional and continental scales are relatively high for both air and wastewater.

Emissions from uses within PVC tend to form the middle band of emission levels. Some uses produce comparatively low local levels of emissions, relative to the overall intensity of total use. For example MCCP use in the compounding process within plastisol coating produce comparatively low local emissions levels to waste water and air. However, as indicated elsewhere in this report, it is expected that the majority of sites using MCCPs in PVC will have more effective emissions abatement equipment in place as compared to the realistic worst case scenario considered for the risk assessment.

Environmental risk characterisation

A need for limiting the risks is identified when the PEC value is greater than the PNEC value, taking into account the impact that further information and/or testing might have on the results of the assessment. Thus, where the resulting 'risk characterisation ratio' (PEC/PNEC) is greater than unity, a need for limiting the risks is identified. Table 2.2 summarises this information in terms of the sectors for which a need for limiting the risks is identified. This takes into account the most recent information on risks (Environment Agency, 2008).

Previous versions of this risk reduction strategy were based on the conclusions of the risk assessment before the addendum to that assessment was updated and new information was taken into account. The results of the additional information have resulted in a number of the risk characterisation ratios being revised downwards. These are highlighted in green. Uses where a need for limiting the risks remains are highlighted in red.

Table 2.2 Sectors where a need for limiting the risks is identified - PEC/PNEC ratios for each use

Use	Release Scenario	Surface Water	Sediment	Terrestrial	Secondary Poisoning: Fish-based food chain [6]	Secondary Poisoning: Earthworm food chain
Production	Site A	0.11	0.28	<1	0.022-0.044	<1
	Site B	0.19	0.49		0.030-0.060	<1
	Site C	0.27	0.69		0.038-0.076	<1
	Site D	0.10	0.26		0.022-0.044	<1
PVC - Plastisol coating	Compounding - O	0.15	0.38	0.05	0.03-0.05	0.16
	Conversion - O	0.44	**1.14**	0.31	0.05-0.10	0.86
	Compounding/conversion - O	0.49	**1.26**	0.35	0.06-0.11	0.97
PVC - extrusion/ other	Compounding - O	0.27	0.69	0.16	0.04-0.08	0.45
	Compounding - PO	**1.03**	**2.64**	0.82	0.10-0.21	**2.26**
	Compounding - C	0.18	0.46	0.08	0.03-0.06	0.23
	Conversion - O	0.62	**1.59**	0.47	0.07-0.14	**1.28**
	Conversion - PO	0.66	**1.68**	0.50	0.07-0.14	**1.37**
	Conversion - C	0.15	0.38	0.05	0.043-0.05	0.16
	Compounding/conversion - O	0.79	**2.02**	0.62	0.08-0.17	**1.69**
	Compounding/conversion - PO	**1.59**	**4.06**	**1.31**	0.15-0.31	**3.58**
	Compounding/conversion - C	0.23	0.58	0.12	0.03-0.07	0.35
Metal working/ cutting	Formulation	**1.64**	**4.20**	**1.33**	0.16-0.32	**3.97**
	Use in oil-based fluids (large facility)	0.71	**1.82**	0.53	0.076-0.152	**1.61**
	Use in oil-based fluids (small facility)	0.66	**1.69**	0.48	0.072-0.144	**1.47**
	Use in emulsifiable fluids	0.15	0.38	0.05	0.026-0.052	0.17
	Use in emulsifiable fluids - intermittent release	**46.60**	**[119 or 2.34]**[3]	**4.34**[4]	0.104-0.208	**12.9**[4]
	Recycling/recovery of metal working fluids – waste transfer facility	0.10	0.27	0.01	0.02-0.04	0.05
	Recycling/recovery of metal working fluids – physico-chemical treatment facility	0.15	0.39	0.05	0.03-0.05	0.17
	Recycling/recovery of metal working fluids – oil re-refining facility	0.17	0.44	0.07	0.03-0.06	0.21
Paints,	Formulation and use - sealants	<1	<1	<1	<1	<1

Use	Release Scenario	Surface Water	Sediment	Terrestrial	Secondary Poisoning	
					Fish-based food chain [6]	Earthworm food chain
adhesives and sealants	Formulation – paints	0.38	0.97	0.25	0.046-0.092	0.76
	Industrial application - paints	0.21	0.54	0.10	0.023-0.064	0.33
	Domestic application - paints	0.10	0.26	<1	<1	<1
Rubber/polymers (other than PVC)	Compounding	0.19	0.48	0.08	0.030-0.060	0.27
	Conversion	0.39	**1.00**	0.26	0.048-0.096	0.78
	Compounding/conversion	0.48	**1.23**	0.33	0.056-0.112	**1.00** [5]
Leather fat liquors	Formulation	0.29	0.74	0.17	0.038-0.076	0.57
	Use - Processing of raw hides	**1.77**	**4.54**	**1.44**	0.172-0.344	**4.30**
	Use - processing of wet blue	**6.79**	**17.40**	**5.74**	0.62-1.24	**17.1**
Carbonless copy paper	Paper recycling (no longer relevant)	0.43	**1.10**	0.28	0.046-0.092	0.88
Regional sources		0.1	0.14	**0.01** [2]		

Based on the environmental risk assessment (ECB, 2005), revised draft addendum (Environment Agency, 2007) and additional assessment (Environment Agency, 2008). Scenarios where a need for limiting the risks has been identified are highlighted in **red** text, with those where there is no longer a need for limiting the risks (as compared to the draft risk assessment and risk reduction strategy of 2004) highlighted in **green.**

[1] O = open process; PO = partially open; C = closed process.

[2] A potential concern was related to "waste remaining in the environment" (no PEC/PNEC ratio is indicated in the risk assessment). This relates to potential loss of MCCPs as part of products during their service life (e.g. due to erosion/particulate losses of particulate matter). The approach for estimating these losses, as well as the actual implications of such losses, was recognised in the environmental risk assessment as having many inherent uncertainties (page 174). It is indicated (page 116) that actual (bio)availability of the MCCPs released to the environment from waste remaining in the environment and the applicability of the available models to predict the resulting environmental concentrations are subject to particular uncertainty.

[3] [ ] = Intermittent release scenario – the risk assessment indicates that it is not clear how this is dealt with in the TGD for sediment.

[4] Assumes dilution of sewage sludge at WWTP before application to soil.

[5] PEC/PNEC ratios for these scenarios are less than 1 if a newer version of the EUSES model is used.

[6] The concentration in fish is estimated taking into account accumulation through the food chain. The range reflects the range for the FAF (1-3).

As can be seen from the above table, the sectors where the risk characterisation ratio is greatest are in use of leather fat liquors and during intermittent releases during use of metalworking fluids.

The risk assessment includes consideration of the potential replacement of SCCPs with MCCPs in metalworking fluids and leather fat liquors (as a result of the recent marketing and use restrictions for use of SCCPs in these applications). Based on the expected move away from SCCPs, a higher background regional concentration of MCCPs could be expected, due particularly to use of MCCPs in metalworking fluids and subsequent emissions. The increased regional concentration was calculated to have the effect that local PEC values for various uses would be greater than the PNEC, for surface water and sediment in particular. These uses include compounding/conversion of PVC and rubber, as formulation and application of paints and formulation of leather fat liquors.

However, this additional assessment included an assumption that all uses of SCCPs in metalworking fluids and leather would be replaced by MCCPs. In reality, whilst there will have been a significant move from SCCPs to MCCPs in these sectors as a result of the marketing and use restrictions, there is also a move away from chlorinated paraffins in general. There has been a modest increase in use of MCCPs in these applications but significantly less than that assumed in the additional risk assessment work. Given these factors, it is considered that the risk reduction strategy should be based on the main results of the risk assessment, including the updates, and not an assumption that all replacement of SCCPs is with MCCPs.

Additional analysis of the risks associated with the various uses of MCCPs has been undertaken (Environment Agency, 2004b) in order to take into account more recent information on the quantities used in each sector, as well as the controls currently in place. The findings of this additional analysis, along with the most recent risk modelling (Environment Agency, 2008) indicate that:

- The level of concern for formulation of metalworking fluids is expected to be significantly less than previously thought with no need for limiting the risks identified for the aquatic, sediment and terrestrial compartments and significantly lower risk characterisation ratios for secondary poisoning than those for use of metalworking fluids[25]. This is because primary treatment of the effluent is assumed to be carried out at all sites prior to discharge to a waste water treatment plant, which leads to a reduction in the emissions estimated from the process. This may not have been the case historically but is reflected in the latest ‘emission scenario document’ for this sector OECD (2004), which updates the emission scenario document used previously for the risk assessment;

- The current situation with regard to disposal of emulsion-based metalworking fluids has now changed and direct release of emulsion-based fluids to the environment without any pre-treatment is unlikely in most cases (as confirmed during work for this risk reduction strategy), although it cannot be completely ruled out. In most cases, therefore, the oil phase will be collected for disposal prior to discharge to drain and the overall level of concern for most sites will be significantly lower than that for the worst-case situation detailed in Table 2.2[26].

[25] The risk characterisation ratios for *formulation of metalworking fluids* were calculated to change as follows: aquatic from 1.64 to 0.11; sediment from 4.20 to 0.28; and terrestrial from 1.33 to 0.02. The values for secondary poisoning were significantly reduced but not eliminated, with that for the fish-based food chain decreasing from 4.7-14.1 to 0.65-1.9 and that for the earthworm-based food chain from 234 to 4.4. However, these updated calculations suggest that secondary poisoning would no longer lead to an identified need for limiting the risks because the calculated PECs were a maximum of 0.44 mg/kg (fish) and 0.74 (earthworm) compared to the PNEC of 10 mg/kg (Environment Agency, 2007).

[26] The need for limiting the risks is eliminated in relation to the aquatic, sediment and terrestrial compartments and the risk characterisation ratios are only just greater than unity for secondary poisoning (maximum value of 3.6 – again the PEC values are all substantially lower than the revised PNEC of 10

The most recent environmental risk modelling takes into account the implications of Directive 75/439/EEC which provides a mechanism by which to prevent the intermittent disposal/releases of water-based metal cutting fluids; however, this does appear to provide a means by which such intermittent release can still occur legally provided a permit has been issued. The data in Table 2.2 provide an indication of estimated PEC/PNEC ratios from waste treatment facilities, assuming that emulsifiable and oil-based metalworking fluids are disposed of in this way rather than released from the metalworking installations; and

- Due to the much-decreased use of MCCPs in carbonless copy paper, the need for limiting the risks in relation to the sediment compartment would be eliminated and the risk characterisation ratios for secondary poisoning would be reduced to a level only just above unity (with a maximum value of 3.6[27]).

Based on the results of the risk assessment, including PEC/PNEC ratios and also the information in Table 2.2, it is possible to draw some conclusions regarding which uses represent the greatest risk to the environment in terms of exposure, as highlighted in Table 2.3.

mg/kg, indicating that there will generally be no need for additional measures, at least at sites where the oil phase is separated prior to disposal).

[27] Again the PEC values for this use are substantially lower than the revised PNEC of 10 mg/kg, indicating that there will generally be no need for additional measures.

Table 2.3 Summary of highest risk characterisation ratios and contribution to overall continental releases

Use	Max RCR	Continental release to waste water (t) [1]	Continental release to air (t) [1]
Use of emulsifiable metal cutting/working fluids (2)	**<u>119 or 2.34</u>**	**<u>1,486</u>**	
Use of leather fat liquors	**<u>17.4</u>**	6.4	
Formulation of metal cutting/working fluids (3)	**<u>4.2</u>**	23	
PVC conversion (incl. combined sites)	**<u>4.1</u>**	6.1[4]	6.1 [4]
PVC compounding	**<u>2.6</u>**	3.3	0.2-2.1
Use of oil-based metal cutting/working fluids	**<u>1.8</u>**	**<u>571</u>**	
Plastics/rubber conversion (incl. combined sites)	**<u>1.2</u>**	3.2	3.2
Carbonless copy paper [5]	0	0	0
Paints (formulation and industrial use)	0.97	13.6	3.4
Formulation of leather fat liquors	0.74	1.9	0.6
Production	0.69	0.1	
Plastics/rubber - compounding	0.48	0.96	0.3
Sealants - formulation and use	<1	Negligible	Negligible
Release over service life – PVC		15.6	**<u>15.6</u>**
Release over service life – rubber/polymers		-	3.2
Release over service life – paints		**<u>35.7</u>**	**<u>95.0</u>**
Release over service life – adhesives and sealants		**<u>305.2</u>**	3.4
Total release (not including waste remaining in the environment) [6]		**<u>2,478</u>**	**<u>132</u>**
Waste remaining in the environment [7]		532 (includes 432 direct to surface water)	2

Notes:

1) RCRs greater than 1 and releases representing more than 5% (water and air combined, excluding waste remaining in the environment) of the contribution to the total continental releases are highlighted in bold, underlined text.

2) Highest RCR and significant release to environment relates to intermittent release – not expected to occur widely and, if treated in waste management facility, no PEC/PNEC ratios all less than 1.

3) Latest information on use and controls in place suggests there may be no need for further limiting the risks.

4) Environment Agency (2008).

5) Due to elimination of use, need for limiting the risks has been removed in this table.

6) Figure would be 398t without releases from formulation and use of metalworking fluids. The risk reduction measures being considered for metal working fluids (for human health) would lead to a marked reduction in the emissions to the environment from these sources giving this lower figure.

7) Includes PVC = 44%, rubber = 12%, paints = 15%, sealants = 30% to water. Also, 1,224 tonnes to urban/industrial soil.

On the basis of the risk characterisation ratios, it can be concluded that the uses of most concern are in use of metalworking fluids (particularly potential intermittent release of emulsifiable fluids) and in use of leather fat liquors. The stringency of controls likely to be required (taking into account those already in place, which will vary by installation), is thus greater than for some of the other uses where a relatively smaller reduction in emissions could reduce exposure to a level where a need for limiting the risks is no longer identified.

In relation to the total contribution to releases to the environment at the continental level, the most significant contributors are use of emulsifiable and oil-based metalworking fluids; release from over the service life (mainly adhesives and sealants); and waste remaining in the environment[28].

Human exposure via the environment

There were no human health effects which lead to a conclusion (iii) in the RAR for exposure via the environment. Therefore, no further risk management activity is required.

PBT assessment

In the addendum to the risk assessment (Environment Agency, 2007), an assessment of the properties of MCCPs against the criteria for a persistent, bioaccumulative and toxic substance was provided[29]. The results of this are summarised in Table 2.4.

[28] Though, as indicated in the risk assessment, MCCPs are essentially bound within a polymer matrix and the actual bioavailability and environmental behaviour of the MCCP is unknown.
[29] This assessment was complicated by the fact that MCCPs are complex substances, containing components with different carbon chain lengths and different numbers of (and positions of) chlorine atoms per molecule.

Table 2.4 Summary of assessment of PBT properties

PBT criterion	Threshold	Conclusions for MCCPs	Comments
Persistence	Half-life > 60 d in marine water or > 40 d in freshwater or half-life > 180 d in marine sediment or > 120 d in freshwater sediment	Meets criterion: not readily or inherently biodegradable	However, some micro-organisms may be capable of degrading MCCPs in the environment
Bioaccumulation	Bioconcentration factor > 2,000	Does not meet this criterion based on highest available BCF	However, the balance of evidence is that the substance meets the screening criteria for bioaccumulation
Toxicity	Chronic NOEC < 0.01 mg/l or CMR or endocrine disrupting effects	Meets criterion	

Based on Environment Agency (2007).

Overall, it was concluded that, although MCCPs are not shown to meet the specific criteria for a PBT substance, there are other data available to suggest that MCCPs (or components thereof) may have the properties of a PBT substance. There are uncertainties over both the persistence and bioaccumulation potential.

It was concluded that further information would be required in order to determine definitively whether MCCPs meet the PBT criteria, including further information to assess the bioaccumulation potential of relevant components, followed (if appropriate), by a further fish feeding study and measurement of biota[30].
The following is a quotation from the risk assessment addendum:

> *When considering the need for further testing it should be born in mind that the substance has already been detected in marine biota (including marine mammals), although the number of reliable monitoring studies is very limited. The trends in levels are unknown, and they may be due (in part at least) to a local source or uses that take place in other regions, or uses that are now better controlled in the EU. It is therefore possible that levels may decrease if the current level of emission does not increase. However, the possibility of long range transport can not totally be excluded. Whilst it is not possible to say whether or not on a scientific basis there is a current or future risk to the environment, in light of:*
>
> - *data indicating presence in marine biota;*
> - *the apparent persistence of the substance (i.e. absence of significant degradation in laboratory screening tests);*

[30] Recent studies have confirmed that MCCPs are present in human breast milk, cows milk and, in some cases, marine fish and marine mammals (though the available data is very limited).

- *the time it would take to gather the information; and*
- *the fact that it could be difficult to reduce exposure if the additional information confirmed a risk;*

consideration could be given at a policy level to the need to investigate precautionary risk management options now in the absence of measured environmental half-life data and confirmatory bioaccumulation data, to reduce the inputs to water (and soil from the application of sewage sludge), including from "waste remaining in the environment".

In this respect it should also be taken into account that an assessment of secondary poisoning for medium-chain chlorinated paraffins has already been carried out, and this leads to the identification of risks from several uses of medium-chain chlorinated paraffins for the earthworm food chain, but possible risks are identified only for one scenario for the fish food chain. A key consideration is therefore whether or not there is any added concern for medium-chain chlorinated paraffins over and above that already identified based on a PEC/PNEC approach[31], given that the PEC/PNEC approach already considers that uptake into aquatic organisms may occur from both exposure via water and via food. Such considerations could include uncertainties around the BCF values for all components of the technical products, and also the very long apparent depuration half-life that has been found recently in mammalian systems. These may introduce uncertainties into the risk assessment of secondary poisoning when extrapolating from the results of laboratory tests to PECs and PNECs related to exposure over an organism's lifetime.

Further testing by industry is ongoing in relation to possible PBT properties. If this information indicates that MCCPs should be considered to be a PBT substance, this will have implications for the way in which the risks associated with MCCPs are managed.

Need for risk reduction measures

There is a need for limiting the risks (taking into account measures already being applied) for all uses where the PEC/PNEC ratio is greater than unity. However, the magnitude of the PEC/PNEC ratio is indicative of the extent to which exposure would have to be reduced in order for the risk to be reduced to a level where no additional measures are required.

Similarly, the overall level of emissions is an important factor to take into account, especially in terms of the overall contribution to the presence of MCCPs in the environment and the conclusions drawn above regarding the possible PBT properties of the substance (as concluded in the risk assessment).

[31] It should also be born in mind that the original risk assessment also identified risks to sediment from many uses of medium-chain chlorinated paraffins (and risks to surface water and soil were also identified from some scenarios) and any risk reduction measures implemented as a result of these conclusions for water, sediment and soil will also have an impact on the amount of medium-chain chlorinated paraffins that would be released to environment in the future.

This risk reduction strategy has been developed on the basis that the releases leading to greatest concern are likely to require more stringent measures to reduce the risks to an ‘acceptable’ level (i.e. where the PEC/PNEC ratio is less than unity). Thus, those with the highest PEC/PNEC ratios are considered to be of greatest concern.

However, the overall quantities emitted also provide an indication of the level of risk associated with emissions of MCCPs: whilst a high PEC/PNEC ratio is indicative of a need to significantly reduce emissions, it does not necessarily provide any information on the extent of the problem and this can be partly indicated by, for example, the overall emissions, though other factors such as the numbers of relevant installations and the risks at the regional level are of relevance (though it has not been possible to identify these aspects in all cases).

There are obviously other factors that need to be taken into account in assessing the overall level of risk (such as the specific ecosystems affected by releases). However, it is not practicable to analyse these impacts with the data currently available.

The results of the PBT assessment[32] and the identified need for further testing and/or possible precautionary action also has implications for the extent to which additional measures are required. The analysis undertaken in this risk reduction strategy has been approached on an objective basis, focused on addressing the risks identified using the PEC/PNEC approach. This has involved attempting to present the relevant implications of different risk management options as a basis for decision making.

As detailed elsewhere in this report, it was the conclusion of several Member States at the 15th Risk Reduction Strategy Meeting that restrictions for several uses of MCCPs were needed on a precautionary basis given current uncertainties regarding the PBT status. This has also been taken into account in this risk reduction strategy, separate from the assessment based on addressing the risks identified on the basis of PEC/PNEC ratios.

[32] The PBT assessment seeks to protect ecosystems where risks are more difficult to estimate and which may not be adequately addressed by traditional risk assessment methodologies (including concerns that PBT substances may accumulate in parts of the marine environment and that the effects of such accumulation are unpredictable in the long-term and would be practically difficult to reverse). For such substances, once the chemical has entered the open seas, any cessation of emission will not necessarily result in a reduction in chemical concentration and hence any effects become difficult to reverse. Equally, because of the long-term exposures and long-life-cycle of many important marine species, effects may be difficult to detect at an early stage. For PBT substances a “safe” concentration in the environment cannot be established with sufficient reliability. The PBT assessment is particularly developed to take into account the unacceptable high uncertainty in predicting reliable exposure and/or effect concentrations hampering quantitative risk assessment. The urgency and stringency of possible measures may be dependent on the potential of the substance to be transported to the open sea. This can be assessed qualitatively by considering the use pattern, volumes and emissions or by using measured data. Open applications and wide dispersive uses of the substance are regarded particularly relevant as well as non-minimised direct discharges from production, formulation and industrial use (European Commission, 2003a).

Any decision to take <u>precautionary action</u> to address the risks associated with MCCPs based on the <u>possible PBT properties</u> will ultimately be a political one and the information presented in this report is intended to inform, but not to make recommendations for, any such decision. This should be taken into account in deciding upon the most appropriate approach to risk management under REACH.

CURRENT RISK REDUCTION MEASURES

Overview

As detailed in Section 2 of this report, there is a need to limit the environmental risks associated with the use of MCCPs in the following applications:

- PVC plastisols – conversion and combined compounding/conversion sites;
- PVC extrusion (and other uses) – compounding (partially open processes only), conversion and combined compounding/conversion sites (open and partially open processes only);
- Metalworking fluids – formulation of metal cutting/working fluids, use of emulsifiable metal cutting/working fluids (intermittent large releases) and use of oil-based metal cutting/working fluids;
- Plastics/rubber conversion - conversion and combined compounding/conversion sites;
- Use of leather fat liquors;
- Recycling of carbonless copy paper (though this use has now ceased).

The identified risks relate to surface water, sediment, the terrestrial environment, the earthworm-based food chain and the fish-based food chain.

In addition, there were concerns raised in the environmental risk assessment regarding 'waste remaining in the environment'[33] and the potential PBT properties of MCCPs, with the latter *potentially* indicating a need for precautionary action to reduce the inputs to water (and soil from the application of sewage sludge), including from waste remaining in the environment.

The risk assessment provides an indication of the uses where a need for limiting the risks is identified. The actual extent to which additional measures are required needs to take into account the risk reduction measures which are already being applied. This section, therefore, provides a review of the various existing measures in place and their implications for reducing the identified risks.

[33] As highlighted in the risk assessment, there are uncertainties regarding the actual bioavailability of MCCPs released to the environment from waste remaining in the environment (potential loss of MCCPs as part of products during their service life e.g. due to erosion/particulate losses of particulate matter) and the applicability of the available models to predict the resulting environmental concentrations.

Marketing and use restrictions on SCCPs

Directive 2002/45/EC restricts the marketing and use of short chain chlorinated paraffins (SCCPs). The Directive and implementing legislation in the Member States[34] prohibit the placing on the market of short chain chlorinated paraffins in concentrations greater than 1% for use in metalworking or for fat liquoring of leather from 6 January 2004.

A UK consultation document on the legislation (Defra, 2003) suggests that the proposed regulations will have minimal impact on UK industry. This is based on consultation with trade associations and key individual firms which would be affected.

A Regulatory Impact Assessment (published with the consultation document) for these regulations identified around 50,000 companies using metalworking fluids in the UK. It was assumed that metalworking companies use either emulsions or neat oils. Those using emulsions would be likely to move to chlorine free emulsions, while those using neat oils would move to MCCP-based neat oils as a result of the restrictions.
It is possible that SCCPs are included as an impurity in other chlorinated paraffins, such as MCCPs. Under the aforementioned regulations, MCCPs would only be permitted to contain a maximum impurity level of 1% of C_{10-13} alkanes (i.e. SCCPs).

The presence of C_{10-13} alkanes in the feedstock for MCCPs could potentially lead to formation of SCCPs within MCCP formulations. However, information from the EU producers of MCCPs indicates that the content of C_{10-13} alkanes is specified at less than 1% for all EU producers. Companies reportedly have no problem in meeting this specification and typical levels are well below 0.5%. ***Therefore, the impact of marketing and use restrictions on SCCPs is not expected to place any knock-on requirements on the marketing and use of MCCPs***. However, it may be the case that imports from outside the EU could include different groupings to characterise MCCPs. It is of note that SCCPs have been included in the candidate list for inclusion on Annex XIV of REACH.

Use in carbonless paper manufacture

A large proportion of European manufacturers of carbonless copy paper (representing 95% of product sold) are members of the Association of European Manufacturers of Carbonless Paper (AEMCP). As detailed in the environmental risk assessment (Environment Agency, 2004), in 1992, the association as a whole agreed to cease using chlorinated paraffins (including MCCPs) in the production of carbonless copy paper. The AEMCP has made available details of its Environmental Safety Policy for the purposes of this risk reduction strategy (AEMCP, 1999). This indicates that use of substances where a risk assessment indicates a PEC/PNEC ratio greater than unity should be ceased. Therefore, members of the AEMCP have essentially made a commitment not to use MCCPs because the PEC/PNEC ratio is greater than unity.

[34] In the UK, these are the Environmental Protection (Controls on Dangerous Substances) Regulations 2003, S.I. 2003 No. 3274.

Anecdotal information indicates that use of MCCPs amongst members of the AEMCP is unlikely to have taken place for around 15 years. As detailed in Section 2, the quantity of MCCPs currently used in carbonless copy paper is very small and use is, as of 2006, expected to have ceased in the EU.

The latest information for the risk assessment (Environment Agency, 2007) indicates that the only endpoint where a need for limiting the risks remains is in relation to risks for sediment. Given that there is currently expected to be no use in carbonless copy paper, it is concluded that the existing risk reduction measures should be sufficient to ensure that the risks are adequately limited[35].

National level measures in EU Member States

Overview

Representatives in the Member States have been contacted for details of any national measures to address the risks associated with MCCPs. Details of these measures are outlined in the following sections. In addition, the following Member States have indicated that there are no national measures in place:

- Cyprus;
- Finland;
- Germany (though see also general information below); and
- Slovakia.

Denmark

In Denmark, there is no legislation concerning use of MCCPs in relation to environmental risks. However, MCCPs have been on the Danish Environmental Protection Agency's 'list of undesirable substances' since 1996. This list is intended to act as a signal to and a guideline for substances which should either be restricted or stopped in the long term. It does not signify that the Danish EPA has decided to recommend prohibition of that substance and other means of restricting use are to be considered[36].

In addition, MCCPs have been assigned a 'MAL Code' in Denmark. The MAL Code relates to workplace exposure and specifies the necessary amount of air supply for dilution of vapours to a safe level. For MCCPs, the factor is given as $0m^3$ air per 10g of MCCPs (Ariel Database, 2004). This is expected to be due to the low volatility of MCCPs.

[35] However, it is noted that any new use in this application in the future could lead to increased risks for the environment.

[36] Such as "classification and labelling, duties on particularly problematical chemicals, stricter standards, voluntary agreements on phase-out, environmental labels, green guidelines for purchasing, positive/negative lists for selected areas, subsidies for substitution initiatives, emission control and information campaigns" (http://glwww.mst.dk/chemi/01040000.htm).

Germany

In Germany, wastes containing chlorinated paraffins, such as metal working fluids with more than 2g halogen/kg, and halogen-containing plasticisers, are classified as potentially hazardous waste and are incinerated (BUA, 1992).

In addition, it is indicated that SCCPs and MCCPs are not used in the production of water-soluble metalworking fluids. Their use in non water-soluble metalworking fluids is limited to a small number of applications. The German Umweltbundesamt has published guidance on substitution of chlorinated paraffins in metalworking fluids[37]. Based on a survey conducted in 1999 (Stolzenberg, 2000), it was indicated that intensive work had been ongoing to replace chlorinated paraffins in Germany since the mid-1980s. It was indicated that the remaining requirements for their use were restricted to a few specialised applications and that less than 10% (probably less than 5%) of SMEs still used these substances.

Around 99% of total metalworking fluid sales within Germany were estimated to be chlorine-free. The decrease in use was understood to have arisen as a result of a variety of drivers including proactive strategies by companies to restrict use (e.g. lists of forbidden substances); occupational hygiene and environmental protection requirements; increasing disposal costs; plant and process optimisation (new formulations, the nature of metal alloys processed, features of tools, changes of process engineering parameters, and changes to applied processing types); as well as regulatory instruments both directly and indirectly[38].

Use of MCCPs in Germany and Austria combined was around 6,700t in 2006 or just over 10% of the total use in the EU-27.

Sweden

In 1991, a goal was set by the Swedish Government to phase-out use of all chlorinated paraffins by the year 2000. Total use of all chlorinated paraffins is reported to have decreased by 75% between 1990 and 1997 (Ospar, 2002). However, it should be noted that MCCPs are still used in Sweden, as identified through consultation for this risk reduction strategy (though in relatively small quantities, based on the Swedish product register).

United Kingdom

In the UK, the *MCCP User Forum* was formed in 2001. It is made up of users and suppliers of MCCPs. It aims to address concerns raised by the UK Chemicals Stakeholder Forum (CSF) and to encourage best practice. The MCCP User Forum has been responsible for developing a realistic targeted plan to reduce risks to the UK environment from MCCPs, looking at where advances can be made quickly, rather than

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37 http://www.umweltbundesamt.de/umweltvertraegliche-stoffe-e/pressure.htm.

38 Such as the Federal Ambient Pollution Control Act BImSchG, Water Protection Act WHG, Chemical Substance Act ChemG, Technical Regulation to Avoid Waste TA Abfall, Environmental Liability Act UmweltHG, Commercial and Industrial Waste Management Act KrW-/AbfG, Environmental Label ‘Blue Angel’ for selected lubricants

seeking to be completely comprehensive. This plan was presented as a commitment to the CSF in December 2002.

The commitment involved working towards achievement of an overall 25% reduction in emissions within 12 months of the date of the commitment, made in December 2002, based on the estimate of emissions at that time. The main focus was on the UK manufacturing and use industries highlighted in the EU Risk Assessment as being of most concern, including the PVC, metalworking and leather industries, although other relevant industries were also covered. The commitment also proposed developing measurement systems to demonstrate the achievement of targets.

According to the Report of the MCCP User Form to the 14th Meeting of the UK Chemical Stakeholder Forum (MCCP User Forum, 2003), the target reduction of 25% over 12 months has been achieved. This is as a result of activities in the applications of MCCPs, reinforced by a change in the market for the products. Specific activities have included:

- A voluntary agreement to operate best practice by companies using more than 50% of the MCCP tonnage in the PVC industry;
- A commitment by formulators of metalworking fluids to operate to and encourage best practice;
- The agreement of the leather industry to adopt best practice should MCCPs be used in leather treatment chemicals (they are not currently used in the UK);
- The development of a good practice guide by the only identified UK formulator of elastomers using MCCPs; and
- In addition, the MCCP User Forum believes that the paints industry and sealant and adhesive industry have demonstrated their commitment to operate to best practice.

Following the report of December 2003, a meeting of the MCCP User Forum was held on 4 March 2004 at which a representative of Entec was invited to attend. Some key findings from this meeting that are of relevance to the risk reduction strategy include:

- It is likely that there exists the potential to increase the commitment made to operate according to the best practice guidance for the industry sectors concerned, both extending sign-up in the UK and extending the commitment to other EU countries;
- Emissions controls in place in practice within the industries of interest may often be much more stringent than those assumed in the environmental risk assessment. For example, it is considered by the industry that PVC plastisol coating processes, particularly wallpaper manufacture, will generally employ exhaust incineration techniques. Also use of emulsifiable metalworking fluids may not involve ‘intermittent release’ of large volumes of metalworking fluids to sewer, as assumed in the risk assessment;
- There is expected to be a natural decline in use of MCCPs in some applications. For example, the engineering industry in the UK is generally in decline and there is expected to be a corresponding decrease in the use of metalworking fluids;

- There is expected to be a downward trend in emissions of MCCPs from PVC manufacture due to increasingly stringent requirements under the 'Pollution Prevention and Control' regime[39], as well as through improvement of abatement equipment as existing equipment reaches the end of its investment lifetime.

The UK Advisory Committee on Hazardous Substances recently considered the progress undertaken under the UK MCCP voluntary agreement. It was considered that:

- For larger metalworking companies, emissions are likely to be controlled through the Integrated Pollution Prevention and Control regime. However, smaller engineering companies would not be covered by IPPC (approximately 130,000 outlets) and these may not be using MCCPs in a "responsible manner". Smaller companies represent only a small percentage of sales but may be responsible for a disproportionate amount of emissions to the environment[40];

- It was considered that there is a major requirement for baseline monitoring figures on MCCP emissions for the PVC sector in particular, against which further emission reductions can be measured. The monitoring data that are available for the PVC sector suggest that emissions are well below the figures estimated under the ESR assessment (ACHS, 2004).

The MCCP user forum is engaging with European trade associations and will explore whether it is feasible to developed commitments to best practice across the EU. They will also continue to monitor the UK market for MCCPs and the impact on emissions, although no further targets have been set for emissions reductions at the current time. It was also concluded that emissions controls at sites using MCCPs in the PVC industry where emissions controls such as thermal oxidation should reduce MCCP emissions close to zero.

National level measures outside the EU

Norway

In Norway, MCCPs are included in the national 'List of Priority Substances' for which emissions are to be substantially reduced by 2010 at the latest.

Norway proposed a ban on 18 substances in consumer products in 2007, including MCCPs. At the time of writing it is understood that the responses to a consultation on this proposed ban were being considered. A brief impact assessment has been provided for the purposes of this risk reduction strategy (SFT, 2007).
Relevant information includes (amongst others):

[39] The Pollution Prevention and Control Regulations 2000 implement the requirements of the IPPC Directive in the UK.

[40] However, there are other legislative and non-legislative controls in place that are likely to ensure that emissions are controlled at smaller sites as well. For example, Council Directive 75/439/EEC (as discussed in Section 3.7 of this report) seeks to prohibit discharge of waste oils to the environment. In addition, in the UK, the regulatory authorities have published guidance seeking to help avoid pollution of the environment by oils and oily waste, which will include MCCPs (see for example, Environment Agency, 2004c).

- Use information: MCCPs are in Norway in products such as lifeboats, insulation/sealants/adhesives but are also imported in products (cables, construction materials such as wallpaper, bags, suitcases, camping chairs, etc.).
- Consumption has increased in Norway due to inter alia the restrictions on the use of SCCPs.
- On the basis of the identified risks and presence in the food chain, they are considered to fulfil the criteria for precautionary action. The main problem is considered to be a general spreading of MCCPs to the environment from many different products. (For the risk reduction strategy, there is not a clear conclusion on this, particularly given uncertainties regarding PBT properties.)
- The prohibition does not consider occupational use (metalworking, polyester for lifeboat production).
- Alternatives are concluded by Norway to exist but are generally more expensive. For lubricants there are no satisfactory alternatives but this is not a consumer product. Where used as a softener only, DINP is considered a good alternative and not much more expensive. There are considered to be alternatives for use as a fire retardant but alternatives are more expensive.
- A prohibition is proposed on consumer products with more than 0.1% by weight in the product's homogeneous parts. Such a prohibition would apply to PVC, paint, lacquer, surface treatment (primarily solvent based), glue, insulation and sealants, polyester (softener, fire retardant), leather preservation and rubber (not an exclusive list).
- This is assumed to reduce emissions by half the quantity on the Norwegian Product Register and a significant reduction in imported articles.
- Replacement with alternative fire retardants will involve costs e.g. for sealants but there are considered to be alternative sealants (e.g. mineral wool). Replacement with alternative softeners was not considered to imply significant additional costs.
- Overall, it was concluded that "there are reasons to expect that the benefits are greater than the costs".

Overall, this document (which is presumed to be subject to change following consultation) reinforces the view that there are not satisfactory alternatives for all MWF uses.

It indicates that substitution in PVC is possible (and this is in line with the RRS conclusions). The conclusions are broadly similar in terms of use of MCCPs as a plasticiser alone i.e. alternatives can be used without significant detriment to technical properties (although the document indicates that alternatives are not particularly more expensive, this is not quantified).

Alternatives for use as a fire retardant (where most MCCP use is assumed to occur) are said to be available but more expensive (this is not quantified).

Canada

SCCPs have been classified as ‘toxic’ in Canada since 1993, under the Canadian Environmental Protection Act (CEPA). MCCPs and LCCPs have not been classified under this system and there are currently no restrictions on the production, distribution or use of these substances in Canada.

However, Environment Canada is currently undertaking a risk assessment on all chlorinated paraffins under the Canadian Environmental Protection Act (CEPA 1999). As with any substance assessed under this Act, risk management activities would only be initiated if the assessment reaches a conclusion of ‘CEPA-toxic’ (noting that no risk management activity has been initiated for SCCPs which were so classified in 1993, under the Canadian Environmental Protection Act 1988).

The latest draft of that risk assessment concludes the following (Environment Canada, 2004):

> *Based on the information available, it is proposed that SCCPs, MCCPs and $C_{18–20}$ and $C_{>20}$ liquid LCCPs are entering the environment in quantities or concentrations or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. Therefore, it is proposed that SCCPs, MCCPs and C18–20 and C>20 liquid LCCPs be considered "toxic" as defined in paragraph 64(a) of CEPA 1999. SCCPs, MCCPs and $C_{18–20}$ and $C_{>20}$ liquid LCCPs are persistent, bioaccumulative and predominantly anthropogenic and thus they also meet the criteria for Track 1 substances under the Government of Canada Toxic Substances Management Policy, making them candidates for virtual elimination.*

United States

The United States Environmental Protection Agency (US EPA) concluded that there is no need to impose restrictions on the manufacture, processing or use of any chain length chlorinated paraffin. In addition, chlorinated paraffins remain excluded from federal hazardous waste regulations (however, C_{12} short-chain chlorinated paraffins must be reported under the Toxics Release Inventory and waste oils containing CPs must be managed as hazardous waste in the state of Washington[41]).

The Water Framework Directive

Under Directive 2000/60/EC, short chain chlorinated paraffins are classified as a ‘priority hazardous substance’ and, as such, a requirement is placed upon Member States to ensure a cessation or phase-out of discharges, emissions and losses. Based on discussions with regulators in the UK, it is expected that the requirement placed upon SCCPs will not place any requirement on MCCPs through the minimal amount of SCCPs present as impurities (generally <0.5%).

[41] http://www.regnet.com/cpia/regulatory.htm.

Annex VIII to the Directive provides an 'indicative list of the main pollutants' that should be controlled in terms of emissions to water. This list includes 'organohalogen compounds', thus including MCCPs. Therefore, there is essentially a requirement for Member States to identify significant emissions of these substances and to introduce controls on emissions as appropriate. Specifically, Member States must collect and maintain information on the type and magnitude of the significant anthropogenic pressures to water bodies, including estimation and identification of significant point and diffuse source pollution, in particular by substances listed in Annex VIII. Member States must also provide a demonstration of the impacts of these pressures and take action to improve the quality of these waters accordingly.

Further consideration is given to whether and how MCCPs could be included on the WFD list of Priority Substances in Section 4.

Integrated Pollution Prevention and Control

A number of the sectors in which MCCPs are used are covered under the Integrated Pollution Prevention and Control Directive 2008/1/EC, including (dependent upon the production quantities):

- Production of MCCPs;
- Metalworking (only large companies in the ferrous and non-ferrous metals sectors);
- Some PVC and plastics compounding/conversion sites; and
- Leather processing (larger sites).

These installations are covered by the IPPC regime because of the nature and size of the installations, rather than due to their use of MCCPs.

The IPPC Directive places a requirement upon Member States to provide authorisation for the installations covered in order to attain 'a high level of protection for the environment taken as a whole'. This is to be achieved by preventing or, where that is not practicable, reducing emissions to air, water and land (as well as including measures concerning waste and energy efficiency).

The IPPC Directive places specific requirements on setting emission limit values for organohalogen compounds which should include MCCPs. In relevant permits under the IPPC regime, emissions of MCCPs can be largely controlled through such emission limits.

Thus, it is likely that in many of the larger companies, controls on emissions of halogenated compounds lead to significantly lower emissions than assumed in the risk assessment. However, the risk assessment process is based on a realistic worst case approach and emissions patterns similar to those assumed in the risk assessment cannot be ruled out, especially for those sites that are not controlled under IPPC requirements. Some additional consideration is given to the extent to which the IPPC regime can be expected to have introduced controls on MCCP emissions in Appendix B.

In addition, the 'local authority pollution prevention and control regime' in the UK places requirements on emissions to air from coating processes which includes spread coating - and hence includes production of PVC wallcoverings – as well as various other coating processes. This is likely to include many companies involved in formulation and application of paints containing MCCPs. Similar controls on emissions to air (which will also introduce controls on emissions to wastewater) are being introduced throughout the EU for certain processes as a result of implementation of the 'Solvent Emissions Directive' (1999/13/EC). Many such companies are introducing techniques such as thermal oxidisers to control these emissions.

As with other legislation that may indirectly control emissions of MCCPs, there are likely to be significant numbers of sites where emissions are sufficiently controlled to ensure that the (local) risks are adequately limited. However, some sites are likely to contribute significantly larger emissions to the environment and this risk reduction strategy is intended to target such uses. The risk reduction strategy takes into account the fact that emissions at some installations can be controlled to levels that will not pose an unacceptable risk (PEC>PNEC) to the local environment.

Legislation on halogenated waste and waste oils

Halogenated wastes – and hence wastes containing MCCPs – are generally classified as hazardous wastes under the European Waste Catalogue[42]. For example, this includes organic halogenated solvents, washing liquids, mother liquors and halogenated filter cakes/spent absorbents from manufacture, formulation, storage and use of basic organic chemicals, fine chemicals, plastics/rubber, as well as shaping of metals. Therefore, under this legislation, companies producing waste containing MCCPs are required to ensure that the waste is disposed of or recovered properly. The European Waste Catalogue includes the definition 'machining emulsions and solutions containing halogens' and wastes containing MCCPs would also be classified as hazardous based on the presence of MCCPs which are expected to be classified as dangerous to the environment.

One of the key concerns for the risk assessment is intermittent disposal of emulsifiable metalworking fluids to drain (this has the highest PEC/PNEC ratio). Releases such as this would not necessarily be prohibited under existing legislation, provided the site operator obtained a relevant permit for such discharges (from the sewerage undertaker in the UK). However, as detailed in Section 2 of this report, most companies are expected to separate the oil phase from emulsifiable fluids prior to disposal to drain (with the oil phase being disposed of by processes such as incineration). Therefore, this concern is not considered to apply at the majority of sites using emulsifiable metalworking fluids containing MCCPs.

[42] Commission Decision of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste, OJ L 226, 6.9.2000, p. 3.

Another relevant piece of legislation relating to this possible disposal route is Directive 75/439/EEC through which Member States are required to take the necessary measures to ensure the prohibition of any discharge of waste oils[43] into internal surface waters, ground water, coastal waters and drainage systems.
Article 4 of Directive 75/439/EEC states that 'Member States shall take the necessary measures to ensure the prohibition of:

- Any discharge of waste oils into internal surface waters, ground water, coastal waters and drainage systems;
- Any deposits and/or discharge of waste oils harmful to the soil and any uncontrolled discharge of residues resulting from the processing of waste oils;
- Any processing of waste oils causing air pollution which exceeds the level prescribed by existing provisions'.

However, Article 6 states that 'In order to comply with the measures taken pursuant to Article 4, any undertaking which disposes of waste oils must obtain a permit. This permit shall be granted by the competent authorities after examination of the installations, if necessary. These authorities shall impose the conditions required by the state of technical development' (Environment Agency, 2008).

This legislation should thus have the effect of generally preventing the disposal of emulsions containing MCCPs but such discharges may still occur if a permit has been obtained.

However, it has been acknowledged that the Directive has not been well implemented and that waste oil collection rates remain too low. In October 2008, the Council adopted a new Directive on waste. Article 21 of this Directive states that:

1. Without prejudice to the obligations related to the management of hazardous waste laid down in Articles 18 and 19, Member States shall take the necessary measures to ensure that:
(a) waste oils are collected separately, where this is technically feasible;
(b) waste oils are treated in accordance with Articles 4 and 13[44];
(c) where this is technically feasible and economically viable, waste oils of different characteristics are not mixed and waste oils are not mixed with other kinds of waste or substances, if such mixing impedes their treatment.
2. For the purposes of separate collection of waste oils and their proper treatment, Member States may, according to their national conditions, apply

[43] Waste oils are defined as any semi-liquid or liquid used product totally or partially consisting of mineral or synthetic oil, including oily residues from tanks, oil-water mixtures and emulsions.
[44] Article 4 sets out a hierarchy for waste of prevention, preparing for re-use, recycling, other recovery and finally disposal (Member States are required to take measures to encourage the options that deliver the best overall environmental outcome). Article 13 requires that Member States take the necessary measures to ensure that waste management is carried out without endangering human health, without harming the environment and, in particular: (a) without risk to water, air, soil, plants or animals; (b) without causing a nuisance through noise or odours; and (c) without adversely affecting the countryside or places of special interest.

additional measures such as technical requirements, producer responsibility, economic instruments or voluntary agreements.
3. If waste oils, according to national legislation, are subject to requirements of regeneration, Member States may prescribe that such waste oils shall be regenerated if technically feasible and, where Articles 11 or 12 of Regulation (EC) No 1013/2006 apply, restrict the transboundary shipment of waste oils from their territory to incineration or co-incineration facilities in order to give priority to the regeneration of waste oils.

Overall, whilst it may be considered irresponsible to dispose of such large quantities of waste containing MCCPs to drain, it is not necessarily considered illegal under the previous waste oils directive and was understood to occur in practice legally (with an appropriate permit) and possibly illegally. This is based on consultation with the Environment Agency, as well as evidence on the metalworking industry in the UK. The new Directive on waste should, depending upon the measures implemented by the Member States, provide a means of limiting risks to the environment.

The aim of this risk reduction strategy is not to target those practices which are already illegal but those which occur under normal conditions of use: disposal of emulsifiable metalworking fluids to drain appears to be permitted in some cases and so is considered as part of this risk reduction strategy; however, this may not be true in the future, depending on the measures taken by Member States. As detailed in Section 2, separation of the oil phase prior to disposal is expected to occur at the majority of sites (and the level of risk associated with those sites will be significantly lower).

Measures implemented by industry in practice

It is important to recognise that the actual controls in place at installations producing and using MCCPs may vary significantly from those assumed in the risk assessment, as a result of a variety of legislative pressures as well as practices adopted in certain industry sectors or companies.

Therefore, many installations will not have associated releases that lead to releases, environmental concentrations and PEC/PNEC ratios that are as high as those assumed in the risk assessment.

For example, it is understood that many PVC compounding and conversion facilities do not have site drains in key areas where releases of MCCPs could take place to waste water and, according to Eurochlor, all PVC converters apply exhaust recovery and incineration (no exceptions have been identified by them).

As a result of various regulatory pressures, including existing emissions control legislation, classification and labelling of MCCPs and perceived possible future restrictions on MCCPs, some firms have taken steps to substitute MCCPs in certain applications which will tend to reduce overall use and emissions as compared to those assumed in the risk assessment[45].

OSPAR Convention

MCCPs are on the *list of substances of possible concern* under the OSPAR Convention (OSPAR, 2004). This list consists of the substances that have been selected on the basis of their intrinsic hazardous properties (persistence, bioaccumulation and toxicity). Based on new data, substances may either be withdrawn from the above list or placed on the *list of chemicals for priority action* which includes those that the OSPAR Commission has determined represent the highest concern due to the amount produced, the degree of hazardous properties and/or the actual occurrence in the marine environment.

Guidance and best practice

In addition to the various legislative and voluntary measures described above, there is also a significant volume of guidance produced within each of the industries concerned, promoting responsible use and disposal of chemicals in general. For example, such guidance includes:

- Guidance in the UK published by *Envirowise* on issues such as 'optimising the use of metalworking fluids', 'cost effective treatment of waste oily water', 'automatic recycling of metal working fluids', 'cost effective management of lubricating and hydraulic oils' (www.envirowise.gov.uk);
- The British Lubricants Federation has a Metalworking Product Stewardship Group which advises on best practice for the control and management of MWFs; and
- Through the MCCP User Forum, guidance has been developed for various sectors including PVC, metalworking fluids, paints, and sealants, with some companies provide best practice guidance on handling, storage, use and disposal of MCCPs.

Summary of implications of current risk reduction measures

It is evident that, through all of the measures discussed in this section, as well as others in place within the sectors concerned, there will be a significant number of sites using MCCPs at which emissions are likely to be much smaller than those assumed in the risk assessment report. Indeed, it is likely that the quantities released from these sites will not pose an unacceptable risk to the environment (i.e. PEC<PNEC).

However, the risk reduction strategy needs to target the 'worst case' sites in relation to releases, and this is the basis of the risk assessment. Therefore, none of the areas where

[45] For example, one company providing information in 2008 (previously identified as using just under 1000t of MCCPs per year) has initiated a project to remove MCCPs from their flooring products. This is a long timescale project, not expected to be complete until the end of 2009 (because of the need to preserve technical properties of the fire retardant flooring materials). The company is mainly looking at use of phosphate ester flame retardants, which are significantly more expensive than MCCPs.

a need for limiting the risks has been identified will be ruled out for the purposes of this assessment.

Table 3.1 Summary of existing risk reduction measures

Measure	Sectors affected	Implications
SCCPs marketing & use restrictions	Metalworking Leather fat liquors	No direct implications for MCCPs Replacement by MCCPs in some neat oils
AEMCP voluntary cessation of use	Carbonless copy paper	Expected to be little or no current use of MCCPs in this application.
Danish EPA – list of undesirable substances	All	Provides signal that substitution (or other measures) desirable in long term
Germany – wastes containing CPs classified as potentially hazardous and incinerated	Metalworking and potentially all uses	Should prevent disposal of MCCPs in e.g. metalworking to water
Germany – various initiatives promoting substitution	Metalworking	Over 99% of metalworking fluids chlorine-free in 1999 (though use still significant in 2006)
Sweden – goal to phase out CPs by 2000	All uses	Reduction in use of CPs by 75% over 1990 to 1997. Still some use in Sweden however
UK – voluntary agreement	PVC Metalworking Leather Rubber/other plastics Paints, sealants and adhesives	Emissions controls may be more significant in practice than assumed in risk assessment (e.g. PVC industry) Reduction in use expected due to decline in manufacturing industry IPPC and other pollution control measures expected to reduce emissions but some smaller companies may not be so well controlled
Water framework directive	All	Includes SCCPs as a priority substance (Annex X) but unlikely to affect releases of MCCPs. Wider controls on organohalogens under Annex VIII unlikely to prioritise MCCPs at present time
IPPC	MCCP production Metalworking (large installations) Some PVC compounding/conversion Leather processing (larger installations)	Requirement to set ELVs, expected to include MCCPs under organohalogen compounds group but no specific ELVs set in EU law or BREFs. Applies to installations with high production levels only.
Legislation on halogenated waste and waste oils	Uses where waste containing MCCPs is produced (e.g. metalworking)	Should prohibit disposal in metalworking fluids to water and drainage (or at least be subject to permits). Separation of oil phase in emulsifiable MWF expected to take place in most installations. New Directive on waste should strengthen controls.
OSPAR Convention – substance of possible concern	All uses	Action to address hazards would be taken if placed on list of chemicals for priority action.

Note – measures for countries outside the EU are not included in this table but are mentioned in the main text.

Table 3.2 provides a broad summary of the implications of the key measures in place for each of the uses of MCCPs where a need for limiting the risks was identified.

Table 3.2 Summary of implications of measures already in place (for uses where need for limiting the risks is identified)

Use	Implications of measures already in place (key points)
PVC	Monitoring data (from e.g. UK voluntary agreement) indicate emissions significantly lower than those in RAR at installations covered. Also, emissions controls expected to be in place in various uses (e.g. exhaust incineration in wallpaper manufacture). Industry has confirmed (2008) that all PVC converters using MCCPs apply exhaust recovery and incineration.
Metalworking fluids	Legislation on waste oils expected to significantly limit release to water, drain, etc. as compared to assumptions in RAR although significant releases may still occur. Recent amendments to legislation expected to improve compliance and this would be expected to reduce risks for metalworking. Extensive substitution in some Member States (e.g. Germany).
Rubber/polymers other than PVC	Measures such as IPPC (for some larger installations) and emissions abatement for air quality considerations expected to have some impact on addressing emissions. However, not targeted at MCCPs specifically. Note that only a small additional reduction in releases would be required to reduce risks to an 'acceptable' level (PEC<PNEC) as the highest PEC/PNEC ratio is 1.23.
Leather fat liquors	IPPC implementation should limit releases at larger installations (though not necessarily specific to MCCPs). Legislation on hazardous waste may also have some impact on controlling emissions through again this is not specific to MCCPs.
Carbonless paper recycling	AEMCP voluntary agreement, etc. expected to lead to no current use. Expected to be little or no need to further limit the risks.

POSSIBLE FURTHER MEASURES

Overview

In the early stages of this project, consideration was given to a range of potential technical and policy options for addressing the identified risks to the environment and to human health via the environment. A limited number of options were recommended for further consideration during the remainder of the project. These options were agreed at the first meeting of the Steering Group and are as follows:

- *Limiting/reducing emissions to the environment via legislation*;
- *Limiting/reducing emissions to the environment via a voluntary commitment*;
- *Restricting the marketing and use of MCCPs through legislation*;
- *Restricting certain uses of MCCPs through a voluntary commitment; and*
- *Implications of revised classification and labelling will also be considered.*

Consideration is therefore given in this section to how these measures could potentially be implemented through legislative or other means.

As detailed in Section 2 of this report, the extent to which additional measures are required to limit the risks will depend upon the extent of the risk already identified. In relation to the identified PEC/PNEC ratios, those uses with a higher PEC/PNEC ratio will obviously need greater action to reduce releases to the environment than those where the identified need for limiting the risks is more marginal. For example, the highest PEC/PNEC ratio for combined compounding/conversion sites using MCCPs in rubber/polymers other than PVC is 1.23 (for sediment), with all other ratios equal to (conversion sites for sediment and combined sites for the earthworm-based food chain) or less than (all remaining endpoints) unity.

In examining the options for risk reduction, the nature of the risk assessment process also needs to be taken into account: the risk assessment is developed on the basis of a ‘realistic worst case’ analysis of predicted environmental concentrations and effects. Therefore, whilst a need for limiting the risks may be identified for particular uses of MCCPs, there will often not be an equivalent level of concern for all sources (sites), and indeed many such sites may not even make a significant contribution to the overall risks.

Controlling emissions through legislation

Background

In terms of legislative controls on emissions, consideration is given herein only to controls that would be implemented through EU-wide legislation. As detailed in Section 3, there is essentially an existing requirement for Member States to identify significant anthropogenic pressures on water bodies and to take action to reduce any pollution accordingly (under the Water Framework Directive). However, this is not currently considered sufficiently specific in relation to providing controls on the risks associated with MCCPs. Similarly, the IPPC Directive requires that emission limit values be set in permits/authorisations for larger installations but this is not specific to MCCPs in all cases and does not link directly to the conclusions of the risk assessment.

Water Framework Directive

Controls specific to MCCPs could be introduced through the Water Framework Directive by their inclusion on the list of 'priority substances'. A first list of priority substances was published in 2001[46] and the Commission is required to review the list of priority substances at least every four years. The 2001 list of priority substances was derived through a 'combined monitoring-based and modelling-based priority setting' (COMMPS) procedure (European Commission, 2001). This involved identification of the substances on the list and determination of which priority substances (PS) should be classed as priority hazardous substances (PHS). The resulting controls required for these two groups are different:

- For PS, the Commission is required to submit proposals for the progressive reduction of discharges, emissions and losses; and
- For PHS, the Commission is required to submit proposals for the cessation or phasing out of discharges, emissions and losses, including an appropriate timetable for doing so, which should not exceed 20 years after the date that these proposals are adopted.

Therefore, inclusion of MCCPs on any revised list of priority substances would provide a legal basis for introducing a requirement to control emissions of MCCPs to or via the aquatic environment. The information detailed in the risk assessment on measured and modelled concentrations of MCCPs in the environment could be expected to lead to prioritisation of MCCPs for control under this legislation.

Under Article 16(2) of the Directive, one of the factors to take into account in the prioritisation of substances for action relates to of risk to or via the aquatic environment identified by risk assessments carried out under the Existing Substances Regulation. The Commission is currently considering prioritisation of substances for selecting additional priority substances and it is envisaged (INERIS, 2007) that substances will be considered as candidates for priority substances when recommendations published in the Official Journal ask for risk reduction/mitigation measures for the protection of the aquatic environment or of humans via the aquatic environment. It is understood that MCCPs could be among these candidate substances due to the conclusions of the risk assessment.

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[46] Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 establishing the list of priority substances in the field of water policy and amending Directive 2000/60/EC.

Following the 15th risk reduction strategy meeting, based on the results of the risk reduction strategy, the following measures were included in a draft recommendation on MCCPs (European Commission, 2008):

- *To consider the inclusion of MCCPs in the priority list of Annex X to Directive 2000/60/EC during the next review of this Annex.*
- *It is recommended that for river basins where emissions of MCCPs may cause a risk, the relevant Member State(s) establish EQSs and the national pollution reduction measures to achieve those EQS in 2015 shall be included in the river basin management plans in line with the provisions of Directive 2000/60/EC .*
- *Local emissions to the environment of MCCPs should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.*

Integrated Pollution Prevention and Control

The IPPC Directive requires all installations covered by Annex I of the Directive to obtain a permit from the national authorities in order to continue operating. Permits place a requirement for the use of Best Available Techniques (BAT) to reduce emissions and the impact on the environment as a whole.

Permits must include emission limit values for pollutants, in particular those listed in Annex III to the Directive, likely to be emitted from the installation concerned in significant quantities, having regard to their nature and their potential to transfer pollution from one medium to another. Annex III to the Directive includes ‘organohalogen compounds’ and companies producing or using significant quantities of these substances will generally have emission limits set, for organohalogens as a whole and/or for specific substances.

In addition, the Directive provides for emission limit values to be established at the Community level. The Council of the EU can set emission limits following a proposal from the European Commission. Such emission limits would apply to the categories of installations listed in Annex I to the Directive.

Table 4.1 provides a summary of the expected coverage of the IPPC Directive in relation to the sectors covered by this risk reduction strategy.

Table 4.1 Coverage of MCCP user sectors by IPPC Directive

Sector	Covered?
Production of MCCPs	Yes. Note – no longer an identified need for limiting the risks.
Polyvinyl chloride (PVC)	Coverage includes larger installations where production of basic plastic materials takes place, in addition to the activities covered by this risk reduction strategy (e.g. where PVC production and compounding take place at the same site). Smaller installations will not be covered.
Metal working/cutting	Some larger companies expected to be covered where production or processing of metals takes place. However, many small installations are not covered.
Paints, adhesives and sealants	Paint formulation not expected to be covered except where production of basic chemicals takes place. In relation to paint application, only the largest companies will be covered (consumption capacity more than 150 kg per hour or 200 tonnes per year). Note – no longer an identified need for limiting the risks.
Rubber/polymers (other than PVC)	Coverage includes larger installations where production of synthetic rubbers or basic plastic materials takes place, in addition to the activities covered by this risk reduction strategy (e.g. where plastic production and compounding take place at the same site). Smaller installations will not be covered.
Leather fat liquors	Larger installations covered. Smaller installations not covered (only applies where capacity is more than 12 tonnes of finished product per day).
Carbonless copy paper	Paper recycling covered where paper and board production takes place and production capacity exceeds 20 tonnes per day.

In addition, controls under the IPPC Directive could extend to companies in the sectors relevant to the risk reduction strategy where one of the other activities in Annex I to the Directive takes place and where the process concerned (e.g. metalworking) is directly associated with the main activity.

Based on the information in Table 4.1, it is evident that several of the activities will be regulated under the IPPC Directive. However, this generally only applies to the largest installations and many of the smaller companies (in metalworking, for example) are not covered by the Directive. Nonetheless, the IPPC regime does provide a basis for ensuring that emissions from those installations covered are adequately controlled (e.g. emissions could be controlled such that concentrations in the local environment do not exceed the PNEC, especially if environmental quality standards were to be applied for MCCPs). Indeed, whilst there may not be specific emission limits for MCCPs at all installations, the more general pollution prevention and control requirements (e.g. abatement techniques and management practices) also have potential to impose controls on emissions of MCCPs.

In addition, through the relevant guidance and implementation by the Member States, more specific requirements on MCCPs could be introduced (for example, the BREF note for the leather tanning industry already suggests that chlorinated paraffins should be substituted). The extent to which this expectation could be realised by Member States is unclear, but there is an opportunity to emphasise this expectation through country-specific IPPC guidance and local permitting and improvement programmes. In

addition, a specific benchmark emission value could be introduced for the relevant regulated activities, following a proposal from the Commission.
Following the 15th risk reduction strategy meeting, based on the results of the risk reduction strategy, the following measures were included in a draft recommendation on MCCPs (European Commission, 2008):

- *Competent authorities in the Member States concerned should lay down, in the permits issued under Directive 2008/1/EC of the European Parliament and of the Council , conditions, emission limit values or equivalent parameters or technical measures regarding MCCPs in order for the installations concerned to operate according to the best available techniques (hereinafter "BAT") taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions.*

- *To facilitate permitting and monitoring under Directive 2008/1/EC MCCPs should be included in the ongoing work to develop guidance on 'Best Available Techniques'.*

Voluntary commitment to control emissions

Voluntary action at an EU level to address the environmental risks and emissions associated with MCCPs could potentially be undertaken as part of the risk reduction strategy. The most appropriate form of commitment would likely take the form of an 'environmental agreement' which would be given specific recognition by institutions of the European Union. The European Commission indicates three possible means by which such agreements may arise:

1. Purely spontaneous decisions initiated by stakeholders where the Commission has neither proposed legislation nor expressed an intention to do so;

2. A response by stakeholders to an expressed intention of the Commission to legislate; or

3. Agreements initiated by the Commission (European Commission, 2004a).

Whilst environmental agreements involve self-regulation by organisations involved (and hence are not legally binding), recognition may be given to such agreements by the Commission, as outlined in Table 4.2.

Table 4.2 Types of Environmental Agreement (European Commission, 2004a)

Environmental Agreement	Description
Self-regulation	Encouragement/acknowledgement given by Commission where the Commission may stimulate the agreement an environmental agreement by means of an exchange of letters with the relevant industry's representatives or a Commission Recommendation. This could also involve a Parliament and Council Decision on monitoring of the agreement.
Co-regulation	European Parliament and Council Directive stipulating that a precise, well-defined environmental objective must be reached on a given target date, including conditions for monitoring compliance. This may also include a follow-up mechanism in case of failure to deliver the objectives (e.g. legislation). Where the Commission proposes co-regulation, it may include key elements based on existing or proposed voluntary agreements, which are satisfactory from the Commission's point of view. These may then be pursued in discussions with the other institutions.

Thus, an environmental agreement could be introduced to reduce emissions of MCCPs from the various sources. This could potentially build upon the co-operation achieved through the commitment of the MCCP User Forum in the UK, as discussed in Section 3. The European Commission (2002a) has indicated that such agreements should present real added value with regard to the level of protection of the environment and also:

- *"evaluation of the agreements should take account of the cost-benefit ratio. Administrative costs should not be higher than those of other available instruments;*
- *"signatories to environmental agreements should represent the majority of the economic sector concerned and should be responsible and organised;*
- *"the objectives of the agreements must be clearly stated without any ambiguity. If the agreement covers a long period, intermediate objectives must likewise be specified. There must be reliable indicators to measure the extent to which objectives have been achieved;*
- *"agreements should be accessible to the public on the Internet, and the same applies to the relevant reports and accounts. Interested parties should be able to express their opinions;*
- *environmental agreements should include a monitoring and reporting system for achieving the objectives;*
- *"agreements should incorporate matters relating to sustainable development and consumer protection."*

Restricting marketing and use through legislation

The analysis in this risk reduction strategy was originally prepared on the basis of considering possible restrictions under Directive 76/769/EEC[47]. Substances controlled in this way were listed in Annex I to the Directive, which also indicates the restrictions that apply in each case. As indicated in Section 3, restrictions on SCCPs have already been introduced for certain uses.

Under REACH, Member States or ECHA, on a request from the Commission, can prepare an Annex XV dossier proposing to include a new restriction to Annex XVII of REACH or amend an existing one. Such a dossier has to conform to the requirements in Annex XV of the REACH Regulation.

Member States have an obligation under Article 136(3) of the REACH Regulation to prepare Annex XV transitional dossiers for substances prioritised under the Existing Substances Regulation where the rapporteur did not forward by 1 June 2008 the risk evaluation and, where appropriate, the strategy for limiting risks, in accordance with Article 10(3) of the ESR. In addition, specific arrangements were made between the Commission and the Member State competent authorities (MSCA) that transitional dossiers should also be prepared for those ESR priority substances where the risk assessments and risk reduction strategies were forwarded, but where the discussions on the assessments were not concluded in the Technical Committee for New and Existing Substances (TCNES) and/or the strategies for limiting the risks were not endorsed by the Risk Reduction Strategy Meeting (RRSM). Transitional dossiers have to be submitted to ECHA by 1 December 2008.

Restricting uses through a voluntary commitment

As an alternative to ensuring adequate controls on environmental emissions, a voluntary commitment could be implemented to restrict certain uses of MCCPs in order to achieve a reduction in the environmental risks. For example, controls could be introduced on those uses that present the greatest risk to the environment or where the industry sectors concerned appear most willing and able to commit to reducing the identified risks associated with MCCPs.

The procedures and requirements for such an agreement would be essentially the same as those for a voluntary commitment on control of MCCP emissions. Restriction use of MCCPs to certain applications through this means would have an advantage over legislation in that use in other applications would not be stigmatised to the same extent. For example, anecdotal information for this risk reduction strategy indicates that some companies have ceased using SCCPs in applications where they are not restricted under Directive 2002/45/EC, because there is a perception that all uses are controlled. Such an effect might be avoided through voluntary action to control certain uses.

[47] Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, OJ L 262, 27/09/1976, 201-203.

Implications of classification and labelling

The majority of the work on this risk reduction strategy was undertaken prior to introduction of new classification for MCCPs. This classification has now been adopted through the 30th adaptation to technical progress of Directive 67/548/EEC and is summarised in Table 4.3.

Member States are required to comply with the requirements of the new Directive by 1 June 2009 at the latest.

Table 4.3 Classification and labelling of MCCPs for environmental and human health effects

Environment	Human health
N - Dangerous for the environment	R64 – May cause harm to breast-fed babies
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment	R66 - Repeated exposure may cause skin dryness or cracking

As a results of the new classification (R64 classification in particular), there are expected to be significant implications for producers and users of MCCPs that may affect their use of the substance and the control measures in place. The European Commission (2002) has highlighted applicable legislation that may arise as a result of the classification and labelling of substances and which may thus affect use of MCCPs. This legislation includes, among others:

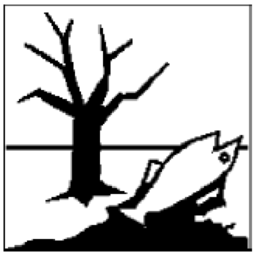
- In relation to *environmental pollution*, Council Directive 96/61/EC (now 2008/1/EC) concerning integrated pollution prevention and control (the 'IPPC Directive');
- In relation to *worker health and safety*, Directive 98/24/EC on the protection of the health and safety of workers from the risk related to chemical agents at work (the 'Chemical Agents Directive'); and Council Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breast feeding (the 'Pregnant Workers Directive'); and
- In relation to *waste management*, Council Directive 91/689/EEC on hazardous waste.

The most wide-reaching implications would be expected to result from the proposed classification in relation to human health effects (as indicated by several consultees for this risk reduction strategy). In particular, under the Chemical Agents Directive and the Pregnant Workers Directive, companies would be required to examine the potential for substitution of MCCPs as the preferred option, with other options including assigning workers to alternative work where there is no risk of further exposure. Therefore, the revised classification could be expected to lead to substitution of MCCPs in cases where there are commercially and technically viable alternatives available and to the reduction of occupational exposure in other cases.

Information provided for this risk reduction strategy confirms that assignment of the R64 risk phrase may have a significant impact the acceptability of MCCPs for downstream users in various uses.

The revised environmental classification may also have implications for downstream users' willingness to use MCCPs, due to the associated labelling and also requirements regarding classification and labelling in relation to transportation. In particular, it is likely that MCCPs and some preparations would be classified as 'class 9' (miscellaneous products) under the Transport of Dangerous Goods Act, 1992 in the UK and equivalent legislation in other Member States.
The specific labelling requirements that would arise as a result of assignment of the *environmental* classification would be as follows:

N	*Dangerous for the environment*
R50	*Very toxic to aquatic organisms*
R53	*May cause long-term adverse effects in the aquatic environment*
S61	*Avoid release to the environment. Refer to special instructions/safety data sheets*



In relation to formulations containing MCCPs, substances classified as dangerous to the environment need to be considered where the concentration of MCCPs is greater than or equal to 0.1% on a weight for weight basis. The risk phrases for preparations that contain a substance classified as R50/53 are as follows:

- Where the concentration is more than 25%, the preparation should be classified as N, R50/53.
- Where the concentration is between 2.5% and 25%, the preparation should be classified as N, R51/53.
- Where the concentration is between 0.25% and 2.5%, the preparation should be classified as R52/53[48].

All of the commercial formulations of MCCPs that are relevant for the life-cycle stages where a need for limiting the risks has been identified are thus expected to be classified and labelled according to their environmental effects. The only one of these life-cycle stages where the concentration may approach a level as low as 0.25% is where emulsifiable metalworking fluids are diluted for use in metalworking. Certain products sold to this application could potentially not be classified as dangerous for the environment because the concentration could in some cases be less than 0.25%[49]. It is also of note that PVC in plastisol form would be classified according to environmental effects but that fused PVC would not.

[48] R50 = very toxic to aquatic organisms; R51 = toxic to aquatic organisms; R52 = harmful to aquatic organisms.
[49] Emulsifiable metalworking fluids will generally contain MCCPs at around 5% of the oil component. These will then be diluted with water, typically at a 1:20 ratio, reducing the concentration of MCCPs to around 0.25% by weight.

Whilst the revised classification in relation to environmental effects is likely to lead to some reduction in the risks associated with MCCPs through improvements in users' emissions containment, this is not considered to be a suitable risk reduction measure for detailed consideration as part of developing the risk reduction strategy. This is because it does not provide the level of certainty required for reducing all of the risks, particularly those of greatest concern (e.g. where the risk characterisation ratios are highest or where the total emissions to the environment are greatest).

In particular, the relationship between the environmental labelling requirements arising through Directives 67/548/EEC and 1999/45/EC and the behaviour of users is poorly understood. Research has indicated that professional users of chemicals show a slightly higher level of comprehension of chemical labels than the general public but that many users only tend to read labels the first time they use a particular product. In addition, users tend to think that products which are used regularly and are easily available to the consumer are unlikely to pose a serious hazard (DTI, 2002). In small firms in particular, around two thirds of users of chemicals questioned in a survey thought that the chemicals they worked with posed little or no risk, though all products concerned had well documented detrimental health effects (HSE, 2000). The impact of labelling as dangerous to the environment in terms of affecting users' behaviour is even less well known.

ASSESSMENT OF POSSIBLE FURTHER MEASURES

Advantages and drawbacks of MCCPs

Advantages

The benefits of chlorinated paraffins in the various applications were outlined in 2002 by the MCCP User Forum (2002) in the UK:

- They are cost-effective **flame retardants** in phthalate-based PVC formulations such as those found in fire retardant wire and cable, and in applications such as mine belting and safety flooring, as well as in a range of rubbers. In paints, they are used as viscosity modifiers, adhesion promoters and to maintain flexibility of the coating in addition to their flame retardant properties;
- They act as **plasticisers** in flexible PVC, providing partial replacement of more expensive phthalates. They impart flame retardancy, improved water and chemical resistance and better viscosity ageing stability together with a reduction in formulation cost. They also act as plasticisers in polyurethane and liquid polysulphide sealants where properties such as their low water solubility impart benefits for use in aggressive biological environments;
- They can be used as a **physical property modifier**, such as for modification of viscosity in polyurethane, improving adhesion in paints and providing adequate tack for adhesives; and
- They are effective **extreme pressure additives** in metalworking in that they can provide a supply of chlorine which forms a chloride layer on metal surfaces, increasing lubrication over a wide range of temperatures.

Drawbacks

For the purposes of this risk reduction strategy, the drawbacks associated with MCCPs relate to the identified risks to the environment. These are outlined in Section 2 of this report.

Potential alternatives for MCCPs

Overview

Possible substitutes for MCCPs are of particular relevance where any risk reduction measures initiate – through direct or indirect means – replacement of MCCPs in particular applications. A considerable amount of work has already been undertaken on the availability and risks associated with substitutes for MCCPs and this has been utilised for this study. In addition, information has been collated through consultation with the relevant sectors on the availability of substitutes for particular applications.

Consultation for risk reduction strategy

Table 5.1 provides a summary of information provided through consultation for this risk reduction strategy. Information was requested on the availability, technical implications and costs of using substitutes for MCCPs in each of the main areas of application. It should be noted that these substitutes relate to those available for individual companies and do not necessarily reflect the availability of substitutes across the sector as a whole. Other information on potential substitutes collated from data sources other than direct consultation with industry is provided in the subsequent sections.

Table 5.1 Potential substitutes for MCCPs based on consultation for risk reduction strategy

Application	Potential substitute	Technical implications	Cost implications
Rubber and polymers other than PVC - (a) conveyor belts and tubes for compressed air in mining industry; (b) bellows for buses, metro and trains; (c) profiles for fire-proof doors	LCCPs	(a) Too brittle for bellows for buses. (b) Concerns with approvals for fire resistance. (c) Substitution appears possible.	€6 million for redeveloping and testing in EU rubber industry as a whole. €375k per year increase in raw material cost for EU industry as a whole.
PVC wallcoverings	Use only primary plasticiser (e.g. phthalate)	Almost identical performance	Raw material cost increase of around 4%
PVC wallcoverings	Primary plasticisers e.g. di-isononyl phthalate	Superior performance in many respects	3% raw material cost increase of the entire plastisol
PVC flooring	Trialkyl phosphates (possibly with borate flame retardants)	Similar performance but possibly subject to staining.	Around €45,000 redevelopment costs and €100,000 cost of substitute for 100t of use (for one company). Another company estimates around €200,000 per 100t of use for substitution with phosphates.
PVC cable compounds	Di-isononyl phthalate (with antimony if flame retardancy required).	Similar performance expected.	DINP approx. 50% more expensive than MCCPs. Antimony around €4000 per tonne (but lower quantities required).
Metalworking	Esters [1]	-	-
Metalworking - tube and wire [2]	No suitable alternatives identified. LCCPs used for some applications.	-	>€3.5 million spent evaluating alternatives

Application	Potential substitute	Technical implications	Cost implications
Paints - anticorrosive primers/topcoats for metals based on PVC-related copolymer [4]	Blend of LCCPs [3]	Not known	Example €5k to €75k reformulation costs for one company.
	Chlorine-free polymer	Not known	€10-15k reformulation costs for one company. Raw material cost 4-5 times that of MCCPs
Paints - outdoor wall paints, acrylics [4]	LCCPs	Good performance	€2k R&D cost for one formulation. €0.8 per kg raw material cost.
Paints - acrylic topcoats; some antifouling paints; some acrylic and epoxy underwater primers [4]	Polybutenes	Further evaluation required	Unknown
Polysulphide sealants [4]	Terphenyls	Inferior	Five times as expensive Total cost €100k

[1] No further information provided.

[2] A more detailed description of the particular issues faced by this company is included in Appendix B.

[3] Long-chain chlorinated paraffins.

[4] No longer any need identified for reducing the risks based on revised PEC/PNEC ratios.

Further consideration is given to the physicochemical properties and possible environmental and health risks associated with a number of the substances identified in the following sections. These include phthalate plasticisers, long chain chlorinated paraffins, and tri-substituted phosphates[50], as described below.

RPA study for UK Chemicals Stakeholder Forum

Risk & Policy Analysts Ltd was contracted to undertake an examination of the availability of substitutes for MCCPs on behalf of the UK Chemicals Stakeholder Forum. The following uses were considered:

- Use in production of PVC articles;
- Emulsifiable and neat metalworking fluids; and
- Leather fat liquors.

The study included consultation with organisations involved in each of these sectors, as well as modelling of environmental risks using the *EUSES* software. Information was presented on availability, technical implications and costs of the potential substitutes. Table 5.2 provides a summary of the main conclusions for each area of application.

[50] Note that triaryl phosphates appear to be more suitable than trialkyl phosphates where flame retardance is an issue, based on information from the European Flame Retardants Association (2004).

Table 5.2 Main conclusions of RPA study on alternatives

Application	Potential substitute	Technical implications	Environmental and health risks
PVC	Phthalates (DINP and DIDP)	Effective plasticisers but do not provide flame retardant properties	EU risk assessment for DINP concluded no need for limiting risks. DIDP concluded need for limiting risks in relation to consumer exposure
	Phosphate esters	Provide flame retardancy	PEC>PNEC values greater than unity but more information required (triphenyl phosphate). Environment Agency undertaking assessments for several phosphate esters
	Inorganic flame retardants (e.g. Sb_2O_3, aluminium trihydoxide)	Perform well at low concentrations	Inadequate data
Metalworking	Sulphurised esters	Suitable for some but not all applications and cause staining, odour, etc. in some applications	No information
	Zinc dialkyl thiophosphate, calcium sulphonates	Suitability uncertain	Insufficient information
	Tributyl phosphate	Not suitable for extreme temperature and pressure	PEC>PNEC values greater than unity but insufficient information available.
	Polysulphides and synthetic sulphurised esters	Cannot cover all applications; information on characteristics is limited	No information
Leather	LCCPs	Questionable	Draft information from Environment Agency risk assessment [1]
	Phosphorus compounds	Unknown but provide flame retardant properties	Unknown
	Vegetable and animal oils	Generally good properties but not flame retardant	Unknown

Source: RPA (2002).

[1] The Environment Agency risk assessment on LCCPs is considered later in this section.

Overall, the conclusions reached were that:

- A single substitute cannot replace all applications in PVC but a combination of known alternatives could adequately and effectively replace MCCPs, although the costs would be higher and risks to the environment and human health remain largely uncertain;
- Metalworking fluids are by far the most difficult area for substitution of MCCPs; and

- Current use in leather processing is believed to be limited to specialised applications and formulators and users are expected to be able to find alternatives to MCCPs should the need arise, although no specific information on the identity and risks from such alternatives was available.

Danish EPA Study - metalworking industry

A study has been undertaken for the Danish Environmental Protection Agency on 'mapping and development of alternatives to medium chain chlorinated paraffins in the metal industry'.

The objective of the project was to promote substitution of chlorinated paraffins for metal working, focusing on heavy duty metal forming, including deep drawing, punching and extrusion - areas where non-chlorinated alternatives have not been generally identified[51]. The project involved:

- Mapping of existing non-chlorinated lubricant systems, through contact with a range of suppliers. Around 50 lubricant systems were identified;
- Technical testing of 20 of the proposed lubricants. Four of the lubricants exhibited promising lubrication properties in simulated tests and were subjected to a further full-scale production test (including a several-step sheet forming of a work piece in stainless steel, including deep-drawing, extrusion and punching). None of the four alternatives tested exhibited sufficient lubricant performance in full-scale tests; and
- Assessment of the health and environmental properties based on a screening of the available data.

It was concluded that replacement of chlorinated paraffins would require extensive reformulation of the lubricant system, rather than simply replacement of the chlorinated paraffin component.

The project involved assigning scores in relation to the environmental and health classification of key components of the reformulated lubricants.
In relation to health and environmental effects, it was concluded that alkyl sulphides (polysulphides) and phosphorus compounds include substances which may cause adverse health and environmental effects. It was also demonstrated that data on the alternatives in terms of health and environmental effects were "substantially poorer". Overall, based on the sparse available data, it was concluded that:

> *"... non-chlorinated lubricants seem to be better than chlorinated lubricants with regard to health and environmental properties compared to chlorinated lubricants. However, some of the lubricants suggested contain component exhibiting a sensitising potential. In addition, many of the lubricants have a content of substances with an environmental hazard potential at the same level as chlorinated paraffins. However, the substances are present at in substantially lower concentrations than chloroparaffins in the chlorinated lubricants.*

[51] Non-chlorinated alternatives were indicated to already exist for less demanding operations such as drilling and milling.

Several of the proposed lubricants contain substances for which no or very limited data on potential health and environmental effects could be retrieved.

Worst case exposure assessments in the working environment have been carried out for two polysulphides and two phosphorous compounds considered to represent the most critical substance groups in non-chlorinated lubricants for metal forming regarding health and environmental effects. The result of this assessment indicates that worst case dermal exposure or inhalation of vapours may involve a risk of adverse effects on health for some of compounds these two groups ...

... The overall conclusion of the project is that further development of non-chlorinated lubricants for heavy-duty metal forming remains in order to obtain technically satisfying alternatives while simultaneously improving the health and environmental properties." (Danish EPA, 2005)

German UBA study – replacement of chlorinated paraffins in PVC

In Germany, a study was published in 2001 (UBA, 2001) that highlighted the following possible substances as alternatives to chlorinated paraffins used as flame retardants in PVC:

- Aluminium hydroxide;
- Magnesium hydroxide;
- Aluminium polyphosphate;
- Zinc borate; and
- Red phosphorus.

It was indicated that these substances have a lower toxic and ecotoxic potential than that for chlorinated paraffins and that their bioavailability is low.

The report quite rightly points out that "it is not known whether and, if so, what technical conversion problems in respect of applications are to be expected through substitution". It is likely that these substances will be suitable in technical terms for some PVC applications.

However, there are also likely to be other applications where these substitutes are not suitable (e.g. as highlighted in the consultation for this risk reduction strategy, the alternatives identified as being suitable by companies manufacturing PVC products did not include these substances). One issue may be the plasticising effect imparted by MCCPs (including when used as a flame retardant), which would not be achieved through use of the above substances.

Existing Substances Regulation risk assessments

A number of potential substitutes for MCCPs have been – or are being – assessed under the Existing Substances Regulation (as have MCCPs). These include several of the phthalates, which companies using MCCPs in PVC have identified as potential substitutes for MCCPs.

The assessment for di-isodecylphthalate (DIDP) concluded that there is no need for risk reduction measures for all environmental endpoints. However, for consumers and for combined exposure, it was concluded that there is a need for limiting the risks. This related to the potential for DIDP to be used as a substitute for other phthalates in toys because of concerns for hepatic toxicity as a consequence of repeated exposure of infants and newborn babies arising mainly by the oral route from mouthing and sucking toys and baby equipment (France, 2003).

The risk assessment for di-isononyl phthalate (DINP) concluded for all environmental endpoints that there is at present no need for risk reduction measures beyond those which are being applied already (France, 2003a).

The risk assessment and risk reduction strategy for DINP and DIDP have been published[52] and do not include recommendations for risk reduction measures to address environmental risks. They do, however, include recommendations to address the risks associated with DINP in toys and childcare articles (these recommendations are now implemented in Directive 2005/84/EC which amends Directive 76/769/EEC).
For di-(2-ethylhexyl) phthalate (DEHP), the risk assessment undertaken by Sweden has concluded that there is a need for limiting the risks for a number of potentially exposed populations. A need for limiting risks to the environment has not been identified, except in relation to the same exposure scenarios that give rise to concern for the indirect local exposure of children.

The identified risks associated with DEHP are summarised in the associated draft risk reduction strategy (Sweden, 2006). It was concluded that, due to the wide spread use and exposure to humans of DEHP and the ability of the substance to cause effects on fertility and foetal development, concerns were identified in the for a number of subpopulations in the following areas:

Children	from toys and childcare articles (oral); multiple pathways
Children as patients	from medical devices in long-term blood transfusion
Newborns as patients	from medical devices in transfusion
Adults as patients	from medical devices in long-term haemodialysis
Workers	in production and industrial use of DEHP;
	in industrial end-use of products containing DEHP
Children (via the local environment)	near plants for polymer processing; several scenarios
	near plants for non-polymer formulation (several scenarios)
	near plants for municipal STP and paper recycling

As discussed in Section 1.2.4, the conclusions of the risk assessment for DEHP, along with other commercial factors, are contributing to a move away from the use of DEHP

[52] OJ C 90, 13.04/2006, p. 10 and p. 13.

to use of DINP. However, both DEHP and DINP are now restricted for use in toys and childcare articles under Directive 2005/84/EC.
The recommended risk reduction strategy for DEHP has been agreed in relation to environmental risks and humans exposed via the environment. These are summarised in Table 5.3.

Table 5.3 Summary of risk reduction strategy for DEHP

Endpoint	Recommended strategy
Humans indirectly exposed via the environment	Within the framework of existing legislative measures under Council Directive 76/769/EEC (Marketing and Use Directive) it is recommended to consider at Community level restrictions for the use of DEHP in industrial installations for processing polymers with DEHP (extrusion, calendaring, spread coating) and for producing sealants and/or adhesives, paints and lacquers or printing inks with DEHP, exempting installations with no emission of DEHP to the environment as well as installations where DEHP emissions are adequately controlled. Adequate control could e.g. be achieved through efficient treatment of exhaust air and aqueous effluents. The efficiency in emissions' reduction should be documented to enable follow up by Member State authorities.
Environment	It is recommended that for the river basins where emissions of DEHP may cause a risk, the relevant Member State(s) establish EQSs and the national pollution reduction measures to achieve those EQS in 2015 shall be included in the river basin management plans in line with the provisions of Council and Parliament Directive 2000/60/EC (Water Framework Directive).

Source: Draft Recommendation Appendices for Bis (2-ethylhexyl) phthalate (DEHP), 29th May 2006.

DEHP has been placed on the candidate list of substances that may be subject to authorisation under REACH (i.e. inclusion on Annex XIV).

OMNIITOX project

The European Chemicals Bureau, Joint Research Centre participated in a research project under the 5th Framework Programme which includes undertaking a comparison of life cycle assessment (LCA) and environmental risk assessment. One case study undertaken as part of this project involved undertaking a comparative LCA on metalworking fluids with and without MCCPs. It involved a holistic comparison of environmental impacts between alternatives and specifically looked at use of metalworking fluids in the pilgering process. The results indicate that it was difficult to obtain data on the composition of metalworking fluids and data on energy consumption during application. The initial conclusions were that:

1. There is no drop-in alternative to MCCPs as an additive in the metal working fluid originally applied for the specific process being examined. A different type of metal working fluid based on sulphurised compounds is applied today (a complete change in the metalworking fluids). This means that a fair comparison of alternatives should take place at the product rather than substance level.

2. The alternatives to MCCPs are likely to lead to increased energy consumption. Unfortunately, data are very limited and therefore insufficient for drawing conclusions.

3. The main environmental impacts seem to be more related to the application of metal working fluids rather than their manufacture (Christensen and Hansen, 2004).

Environment Agency - National Assessments of aryl phosphates

The European Flame Retardants Association (EFRA, 2004) has identified certain phosphate esters that may be used as potential substitutes for MCCPs in PVC and certain other polymers, *where fire performance requirements of the final product are an issue*. This is detailed in Section B2.3 of Annex B, with the potential substitutes identified as follows:

- Cresyl diphenyl phosphate (CDP);
- Tricresyl phosphate (TCP);
- Trixylyl phosphate (TXP);
- Isopropylated triphenyl phosphate (IPP);
- 2-ethylhexyl diphenyl phosphate (ODP - octyl diphenyl phosphate); and
- Isodecyl diphenyl phosphate (IDDP).

The Environment Agency for England and Wales is currently undertaking a number of national risk assessments for various phosphate esters that may act as flame retardants in PVC formulations. Whilst these assessments are not yet complete, draft information on preliminary worst case PEC/PNEC ratios and PBT assessment have been provided. These assessments are not intended to provide a basis for comparison between the different aryl phosphates themselves.

These assessments represent a good basis for setting out the current understanding of the potential risks from these substances, whilst recognising that the report sets out numerous additional areas where further information would be required to better understand the risks.

Table 5.4 Preliminary worst-case risk assessments for certain aryl phosphates

Substance	PEC/PNEC ratios for PVC
Cresyl diphenyl phosphate (CDP);	Between 1 and 10 for surface water, sediment and soil
Tricresyl phosphate (TCP);	Between 10 and 100 for surface water Between 100 and 1000 for sediment and soil
Trixylenyl phosphate	Not indicated as used in PVC.
Isopropylated triphenyl phosphate (IPP);	Between 1 and 10 for surface water and secondary poisoning (earthworm food chain) Between 10 and 100 for sediment and soil.
2-ethylhexyl diphenyl phosphate (ODP - octyl diphenyl phosphate); and	Between 1 and 10 for secondary poisoning (fish food chain) Between 10 and 100 for soil and secondary poisoning (earthworm food chain) Between 100 and 1000 for sediment.
Isodecyl diphenyl phosphate (IDDP).	Between 1 and 10 for secondary poisoning (fish food chain) Between 10 and 100 for surface water soil and secondary poisoning (earthworm food chain) Between 100 and 1000 for sediment and soil.

Source: Environment Agency (2008b).

The level of information available for these substances is substantially less than that available for MCCPs. Therefore, it is not possible to make a comparison on a like-for-like basis (the PEC/PNEC ratios for these substances are indicated as preliminary and worst-case).

However, based on this information, it is clear that substitution of MCCPs with these alternatives in PVC would not necessarily lead to a reduction in risks (given that there is a potential need to reduce the risks based on the preliminary information available). Whilst such substitution would reduce the specific concern associated with MCCPs, as well as addressing possible wider environmental contamination issues, the overall environmental risk may not be removed (one risk may simply be replaced by another – perhaps equivalent or even greater – risk).

Based on a review of potential PBT properties in the same document, it was indicated that "only two of the substances cannot be excluded as PBT substances. Trixylenyl phosphate has a BCF of 1900 l/kg and was found to meet the first stage screening criteria for P or vP … this substance also possibly meets the T criterion and is therefore considered to meet the screening criteria for PBT". "Tris(isopropylphenyl) phosphate is inherently biodegradable, but the information does not allow confirmation of it meeting the specific criteria, and has a BCF of 1,986 l/kg, which is just below the limit of 2,000 l/kg. The estimated chronic NOEC of 0.006 mg/l indicates that this substance is possibly toxic, and the substance is therefore considered to meet the PBT screening criteria."

Environment Agency Risk Assessment on LCCPs

The Environment Agency is currently undertaking an environmental risk assessment for LCCPs. Whilst the results have not yet been published, draft information has been made available for the purposes of this risk reduction strategy (Environment Agency, 2008c). Table 5.5 provides a summary of the conclusions of the *draft* risk evaluation report for each environmental compartment.

Table 5.5 Conclusions of draft risk evaluation report for LCCPs

Compartment	Conclusions
Surface water	PNEC/PNEC ratios are <1 for all scenarios and so it is concluded that long-chain chlorinated paraffins present a low risk to this compartment.
Sediment	PEC/PNEC ratios are <1 for all scenarios except for the intermittent release scenario for use of C18-20 liquid chlorinated paraffins in emulsion based metal cutting/working fluids. The relevance of this scenario to the current use of long-chain chlorinated paraffins, and the current fluid disposal practices within the industry, is not clear.
Soil	The PEC/PNEC ratios are <1 for all scenarios considered. Therefore the risk to the soil compartment from production and use of long-chain chlorinated paraffins is low.
Atmosphere	Neither biotic nor abiotic effects on the atmosphere are likely because of the limited atmospheric release and low volatility of long chain chlorinated paraffins. Some components of the commercial products may have properties that may mean that long range transport via the atmosphere is a possibility. This issue should be considered further in the appropriate international fora.
Secondary poisoning – fish food chain	PEC/PNEC ratios are all very low. Therefore it can be concluded that a risk of secondary poisoning via the fish food chain is low for long chain chlorinated paraffins.
Secondary poisoning – earthworm food chain	For the earthworm food chain, risk characterisation ratios >1 are obtained for the C18-20 liquid chlorinated paraffins for two scenarios only. These are the use in emulsifiable metal cutting/working fluids where intermittent disposal to waste water is assumed, and the use in textiles. All other scenarios lead to risk characterisation ratios <1.
Marine	The PEC/PNEC ratios are <1 for the majority of scenarios, indicating a low risk to the marine compartment. However PEC/PNEC ratios >1 are obtained for marine water and marine sediment for use in metal cutting/working fluids (intermittent release scenario) and for marine sediment for use in textiles.

Source: Environment Agency (2008c).

An assessment of the PBT status of LCCPs was made using the available measured and calculated data. The available data suggested that long-chain chlorinated paraffins do not meet the screening criteria for a PBT substance.

The assessment makes recommendations about the significance of certain data gaps/data uncertainties, and suggests where further research should be focussed.

Appendix C provides a summary of some of the properties of LCCPs, as compared with MCCPs (and other substances). This is based on a previous draft of the risk assessment for LCCPs (Environment Agency, 2001).

Environment Agency risk assessment on polysulphides

Certain polysulphides have been identified as potential alternatives to use of MCCPs in metalworking fluids. The Environment Agency (2008d) has undertaken work to assess the environmental risks associated with di-(tert-C_9 and C_{12} alkyl) polysulphides. Based on the draft results of this assessment, preliminary risk characterisation ratios have been developed for the following substances: di-(tert-nonyl) polysulphide, di-(tert-dodecyl) polysulphide and di-(tert-dodecyl) pentasulphide:

- For all three substances, high preliminary PEC/PNEC ratios (ranging from around 3 to 150) were identified for surface water (for use of neat and emulsifiable metalworking fluids).
- For all three substances, high preliminary PEC/PNEC ratios (ranging from around 1.3 to 1,500) were identified for sediment (for all stages, including formulation, use of neat and emulsifiable metalworking fluids, waste treatment and the regional assessment).
- For all three substances, high preliminary PEC/PNEC ratios (ranging from around 1.6 to 500) were identified for the terrestrial environment (for formulation, use of neat and emulsifiable metalworking fluids and the regional assessment).
- For all three substances, high preliminary PEC/PNEC ratios (ranging from around 3 to 580) were identified for the secondary poisoning via the earthworm food chain (for formulation, use of neat and emulsifiable metalworking fluids and for waste treatment[53]) but not via the fish food chain.
- High preliminary PEC/PNEC ratios were also identified for marine water and marine sediment for all three substances and for various life-cycle stages.

With regard to potential PBT properties, "the overall conclusion is that the substances meet the P and vP criteria on screening data, and may meet the B and T criteria. "

Research by the Netherlands on alternatives to MCCPs

Following a request from the UK for additional information to support several Member States views that further marketing and use restrictions would be appropriate for MCCPs, the Netherlands provided additional information on the potential for use of alternatives for metalworking and PVC.

In relation to metalworking, a number of companies operating in the Netherlands were interviewed by telephone (RIVM, 2008). In general this resulted in the following conclusions:

- *"In principle the metal working industry avoids the use of chlorinated compounds*

[53] The latter for two of the three substances only.

- *A few heavy operations (e.g. deep drawing) are exceptions, because no alternatives are available (yet). Without MCCPs there is a high risk of cracks and other instabilities of the end product.*
- *About 5-10% (but probably closer to 5%) of the products for metal working industry still contain MCCPs*
- *A US EPA report [on] "Alternatives to VOC emitting petroleum based lubricants and chlorinated paraffin lubricants: minimizing the health and environmental consequences". In this report it is concluded that there are suitable alternatives to lubricants containing chlorinated paraffin additives and that this finding suggests that the chlorinated paraffins could be phased out."*

A brief review of this latter document has been undertaken. The report provides some useful examples of some specific applications where substitution has been possible and (limited) information on the alternatives used.

Overall, the results suggest that substitution of MCCPs in metalworking fluids is possible in some but not all applications.

For the PVC industry, several PVC companies in the Netherlands were interviewed by the Dutch competent authority (by telephone). In general this resulted in the following conclusions:

- *"In principle chlorinated compounds are no longer used and definitively not in consumer products;*
- *In PVC tubing it may still be used to get a smooth surface and improve the abilities for gluing them together [an opinion];*
- *The possibilities of nano-clay as a flame retardant [are currently being] investigated, but [the] risks of this alternative are still unknown;*
- *In some transport belts MCCPs are still used as flame retardants (for 90% used on airports);*
- *For transport belts total usage of MCCP containing PVC certainly less than 10 [tonnes].*
- *In many cases MCCPs are replaced by phosphates or zinc compounds (e.g. in food applications)."*

This provides some useful additional information on use of MCCPs in the Netherlands. The use in transport belts and tubes seems to confirm information from the risk reduction strategy (though there may be some differences in terms of whether used in PVC or rubber/other polymers).

Phosphates as alternatives have been identified as potential alternatives elsewhere in this risk reduction strategy report (and indeed they will already be used in various applications because MCCPs do not by any means constitute the whole of the market). Use of zinc compounds has also been highlighted in the German UBA study (see Section 5.2.5).

Overall, the information from the Netherlands confirms other findings in this risk reduction strategy, namely that alternatives to MCCPs can be and are used in various applications, but that there are some applications where substitution is less feasible. Any decision on whether requiring substitution through a restriction is the most suitable risk reduction option must also be informed by considerations of technical and economic feasibility (the above information suggests that this is feasible in some cases), as well as whether use of alternatives is likely to result in reduced risks for health and the environment (this is not considered in the above information from the Netherlands but is considered elsewhere in the overall assessment of alternatives).

Information from Sweden

Following a request from the UK for additional information to support several Member States views that further marketing and use restrictions would be appropriate for MCCPs, Sweden provided additional information on the potential for use of alternatives for metalworking and PVC (KemI, 2008).

KemI has received information on a new flame retardant for PVC that is said to show good compatibility with plasticisers and to be environmentally friendly[54]. It is understood that this product is still under development and the following information is provided on the company's website:

> *"Tests of the recently developed variation of Apyrum have shown improved flame retardant properties and good compatibility with softeners, as well as almost negligible effects on the physical properties of materials. Moreover, DEFLAMO estimates that the levels of Apyrum needed to be added to a mixture can be less than those of flame retardants that are more environmentally hazardous.*
> *"DEFLAMO is on the brink of a major industrial breakthrough and is in the process of expanding its sales organisation. DEFLAMO also plans to set up a production facility in Sweden during 2008-2009."*

From the publicity information, the manufacturers seem to be of the opinion that this alternative would reduce risks and achieve good/improved flame retardancy.
It appears that this alternative is at a relatively early stage of development and that it would not necessarily be available as an alternative to MCCPs in the short term. However, this may be a potential alternative to MCCPs for use in this application (PVC). The website indicates that the substance is "an environmentally friendly system based on a variety of salts that are classified and approved as food additives ... poses no harm to the human body and has a unique environmental profile." However, information on the specific substance(s) is not provided.

Kemi also provide information suggesting that, given the wide range of PVC plasticisers available, it should be possible to find alternatives in all circumstances. There may however be consequences of substitution e.g. extra cost and possible reduction in fire resistance. Data sets will need to be generated for some possible

[54] http://www.deflamo.se/mbo/content/view/231/1//%20/lang,en/.

substitutes and in the meantime it should not be assumed that they will have a lower risk profile than MCCPs.

With regard to one large PVC flooring manufacturer in particular, Kemi indicate that the company stopped using MCCPs in PVC flooring in 1989 and now use the DINP instead. DINP is more expensive than MCCPs.

They also provide information on ongoing work to replace MCCPs at another PVC-flooring manufacturer (producing anti-slip and safety flooring with high demands on fire resistance. The outcome of discussions with this company is discussed in Section 3.9 of this report.

Kemi also provide information following discussion with one of the metalworking companies consulted for this risk reduction strategy. This company has substituted MCCPs with LCCPs in certain applications and Kemi also highlight that, for drawing of pipes and for pilgering alloys that are more difficult to work and if the dimensions are larger, the company has not yet been able to identify suitable alternatives. The company has started a project looking into chlorine free substitutes and studies looking at recycling/regeneration of used MCCPs are also ongoing. According to this company, there is no significant difference in cost between MCCPs and LCCPs but to use chlorine free alternatives would cost about twice as much according to preliminary results from on-going industry studies.

Alternative materials and techniques

The above sections consider the identified potential chemical substitutes for MCCPs in the various products in which MCCPs are used. Whilst the majority of the substances considered are not direct ‘drop-in’ substitutes (because some reformulation of products and other modifications is likely to be required), they are substances that could (potentially) be used without changing the overall product significantly.
However, there are also other potential alternatives to the actual articles in which MCCPs are used and the functions which these fulfil.

To fully understand the implications of using these types of alternatives would require significant analysis and the currently available techniques make such an approach problematic (as highlighted by the Omniitox study referred to above for one use of MCCPs, amongst many, in metalworking fluids). However, some consideration has been given in Table 5.6 to the types of non-substance alternatives that could potentially be used for the uses of MCCPs where a need for limiting the risks is identified based on the PEC/PNEC ratios.

Table 5.6 Potential non-substance alternatives for main MCCP uses of concern

Use	Potential substitutes	Implications of use
PVC wallcoverings	Non-vinyl wallpaper Painted walls	No use of MCCPs or other substances with potential effects on environment (in coating) Cost implications for PVC and wallcoverings industry Reduced consumer choice
PVC flooring	Linoleum, wood, stone/slate tiles	Possible implications for other environmental impacts (e.g. higher energy use) Potentially higher cost implications for end users/consumers
PVC cables	Polyethylene, polypropylene, fluoroplastics, others	Requires addition of other additives (e.g. heat/UV stabilisers, flame retardants), some with unknown risk profiles. Flame retardancy requirements can be achieved Production costs 50-200% higher (additional costs for overall electrical installation 10-20% higher) (UBA, 2001).
PVC – others (e.g. extruded products)	Wide range of products – not practicable to identify alternatives.	
Metalworking fluids	Improved precision casting techniques	May negate the use for MCCPs in some applications. Not suitable for all applications where MCCPs used.
Leather	Alternative materials (e.g. other textiles)	Environmental implications, costs and technical implications dependent upon alternatives used and not considered further due to range of potential alternatives.
Rubber / plastics other than PVC	Non-substance alternatives not identified for main uses (conveyor belts in mining, bellows for buses/metros, fireproof doors).	
Carbonless copy paper	Electronic copying, etc.	Removes requirement for use of MCCPs. Cost and practicality implications expected in some cases.

Note: Potential alternatives are not considered here for uses of MCCPs where the identified PEC/PNEC ratios are below 1.

Where MCCPs are used in safety critical or high specification products (e.g. flame retarded plastics, metalworking fluids), it is evident that the range of potential alternative materials/techniques is more limited than for other uses where MCCPs are used in achieving a desired aesthetic effect (e.g. wallcoverings, leather).

If MCCPs and the products in which they are used were to be replaced with alternative technologies, this would require a shift from one supply chain to another (existing or new) supply chain. For example, this might involve shifting from the *PVC – additive (formulation) – wallcovering* supply chain to an existing supply chain involving production of non-vinyl wallcoverings. In this case, there would be cost implications for the producers of PVC, formulators and wallcovering manufacturers. There would be financial benefits for the producers of the alternative wallcoverings and, in terms of ongoing economic implications, there may be no economic loss. However, there would be costs associated with the need to abandon the equipment used in the products involving MCCPs prior to the end of its useful economic life that would not be offset by the benefits to the supply chain involving the alternatives.

The consultation undertaken for this study has indicated that the most likely response of companies using MCCPs in the various products would be to seek substance-based alternatives. This is in part a facet of the fact that these companies may not generally be involved in production of alternative products (e.g. non-PVC cabling). In practice, therefore, it is likely that any measure that would require replacement of MCCPs would lead to some uptake of alternative substances and some uptake of alternative products. The extent to which each route is taken will depend upon the availability (and cost) of alternative substances, technical considerations in relation to the end products, as well as various other factors.

Conclusions on alternatives

Overview

The following sections provide the conclusions reached for each of the main applications where a need for limiting the risks is identified regarding the potential suitability of alternatives (i.e. those identified as potentially most promising for key applications). The following issues are considered:

- Availability;
- Human health risks;
- Environmental risks;
- Technical feasibility;
- Economic feasibility.

PVC

Table 5.7 provides a summary of the conclusions drawn on potential alternatives to use of MCCPs in PVC.

Table 5.7 Summary of potential alternatives for use in PVC

Criterion	Conclusions
Availability	Available alternatives on the market include: ▪ LCCPs; ▪ Phthalates (e.g. DINP); ▪ Tri-alkyl phosphates; ▪ Aryl phosphates ▪ Inorganic compounds (e.g. aluminium hydroxide, aluminium polyphosphate) Not all are available/suitable for all PVC uses.

Criterion	Conclusions
Human health risks	No need for limiting risks identified in risk assessment for DINP. Several inorganic compounds expected to pose lower risks than MCCPs. Less information available on human health risks for several alternatives.
Environment risks	No need for limiting risks identified in risk assessment for DINP. Draft environmental risk evaluation report for LCCPs (Environment Agency, 2008c) indicates generally low risks but PEC/PNEC ratios above 1 for some uses. Less information available for aryl phosphates than for MCCPs. Preliminary worst case risk assessment (Environment Agency, 2008b) suggests high PEC/PNEC ratios for various applications. Several inorganic compounds expected to pose lower risks than MCCPs.
Technical feasibility	LCCPs suitable for some applications. Phthalates (e.g. DINP) generally suitable where high fire resistance is not required. Phosphate esters broadly suitable where high fire resistance is required. These are the most suitable identified alternatives based on information available for this risk reduction strategy.
Economic feasibility	LCCPs: perhaps 20% to 160%[1] higher purchase price for compared to MCCPs (dependent upon application and formulation used and by analogy with other uses). Phthalates (DINP) around 60% more expensive than MCCPs. Phosphate esters significantly more expensive than MCCPs (e.g. up to 4 times price based on information in Appendix B, confirmed by industry (Eurochlor, 2008)) Additional costs for reformulation, product approval, etc.

[1] 20% based on consultation, for use in rubber/polymers other than PVC. €375,000 increased cost for assumed 3,500t use in this application equates to around €100 per tonne more expensive (MCCP price assumed to be €500/t). 160% based on information from a company using MCCPs in paints (suggesting increased cost of €0.8/kg for use of LCCPs).

Metalworking fluids

Table 5.8 provides a summary of the conclusions drawn on potential alternatives to use of MCCPs in metalworking fluids.

Table 5.8 Summary of potential alternatives for use in metalworking fluids

Criterion	Conclusions
Availability	Alternatives available for some applications. These vary across uses and include e.g. polysulphides, tributyl phosphate.
Human health risks	May be a risk of adverse effects for some compounds e.g. certain polysulphides and phosphorus compounds (Danish EPA, 2005).
Environment risks	Potentially significant environmental risks associated with e.g. polysulphides (see e.g. Environment Agency (2008d). Environmental risks will vary significantly according to the type of alternative used.

Criterion	Conclusions
Technical feasibility	Extensive reformulation of lubricant system would generally be required. Some alternatives are technically suitable for some applications and substitution has taken place in certain applications (see elsewhere in this report). Given the broad range of products involved (this is a very large and diverse sector), it has not been possible to identify specific alternatives for different applications. Uses where substitution seems most difficult include: deep drawing; punching; extrusion; pilgering; forming; drilling; tapping; rimming; threading; boring; broaching.
Economic feasibility	Cost of using alternatives highly variable across uses. Significant investment costs for some uses (including R&D) as outlined elsewhere in this report, with no alternatives identified for some uses.

Rubber and polymers other than PVC

Table 5.9 provides a summary of the conclusions drawn on potential alternatives to use of MCCPs in rubber and polymers other than PVC.

Table 5.9 Summary of potential alternatives for use in rubber and polymers other than PVC

Criterion	Conclusions
Availability	LCCPs identified as a potential substitute for e.g. conveyor belts and tubes for compressed air in the mining industry; bellows for buses and trains; profiles for fire-proof doors. Other flame retardants and non-fire-resistant formulations are used in various other rubber and polymer formulations (though these are not generally the subject of this risk reduction strategy).
Human health risks	LCCPs: Not known in detail. Some evidence for possible carcinogenicity and reproductive effects [1].
Environment risks	Draft environmental risk evaluation report for LCCPs suggests relatively lower risks than for MCCPs but PEC/PNEC ratios >1 for some uses (but not for use in rubber).
Technical feasibility	Suitable in some applications (e.g. profiles for fire-proof doors). However, reportedly use leads to a too-brittle end product in certain conveyor belts and concerns with approvals for fire resistance in bellows for buses/trains.
Economic feasibility	Industry estimates €6 million for redevelopment and testing in EU as a whole. Possible 20% increase in (ongoing) raw material costs (€375,000 per year).

NTP (1986): Toxicology and carcinogenesis studies of chlorinated paraffins (C_{23}, 43% chlorine) (CAS No. 633449-39-8) in F344/N rats and B6C3F1 (gavage studies), US National Institutes of Health publication no. 86-2561.

Leather fat liquors

Table 5.10 provides a summary of the conclusions drawn on potential alternatives to use of MCCPs in leather fat liquors.

Table 5.10 Summary of potential alternatives for use in leather fat liquors

Criterion	Conclusions
Availability	Alternatives understood to be available including LCCPs, phosphorus compounds, vegetable/animal oils.
Human health risks	LCCPs: Not known in detail. Some evidence for possible carcinogenicity and reproductive effects [1]. Unknown for other applications.
Environment risks	Draft environmental risk evaluation report for LCCPs suggests relatively lower risks than for MCCPs but PEC/PNEC ratios >1 for some uses (but not for use in leather fat liquors).
Technical feasibility	Vegetable and animal oils generally provide good technical performance (RPA, 2002). Unknown for other applications. Note that Cotance indicated agreement with restrictions on marketing and use (controlling MCCPs to a level that is safe for the environment).
Economic feasibility	Use of LCCPs would reportedly increase raw material costs by around 20% compared to MCCPs (around 2% for the entire fat liquor). Unknown for other applications.

NTP (1986): Toxicology and carcinogenesis studies of chlorinated paraffins (C_{23}, 43% chlorine) (CAS No. 633449-39-8) in F344/N rats and B6C3F1 (gavage studies), US National Institutes of Health publication no. 86-2561.

Overview of analysis of measures

Table 5.11 summarises the key actions that would likely be required in general terms in the implementation of each of the possible risk reduction measures.

The Technical Guidance Document on development of risk reduction strategies (European Commission, 1998) requires that an analysis of the advantages and drawbacks of risk reduction measures only where marketing and use restrictions are recommended. The UK Government's policy is to conduct such an analysis on all identified risk reduction options.

Table 5.11 Actions required under each risk reduction option

	Administrative measures	Technical measures
Legislation to control emissions	Authorities to: • Develop and implement legislation. • Identify suitable emission limit values (and environmental quality standards) for sectors. Industry to: • Identify and quantify emissions (provided suitable techniques are available).	Industry to: • Implement suitable emissions abatement techniques. Authorities to: • Ensure approval of method for environmental monitoring.
Voluntary action on emissions	Authorities to: • Identify sufficient coverage within industry and gain approval to specific requirements. • Agree suitable emission limits. Industry to: • Agree to requirements of voluntary agreement. • Agree suitable emission limits.	Authorities to: • Ensure approval of method for environmental monitoring. Industry to: • Implement suitable emissions abatement techniques.
Legislation on marketing and use	Authorities to: • Develop and implement legislation. • Monitor success of legislation.	Industry to: • Identify suitable alternatives. • Reformulate products. • Purchase/incorporate alternative substances.
Voluntary agreement on use	Authorities to: • Identify sufficient coverage within industry and gain approval to specific requirements. Industry to: • Agree to requirements of voluntary agreement.	Industry sectors covered to: • Identify suitable alternatives. • Reformulate products. • Purchase/incorporate alternative substances.

As recommended in the Guidance, the options for reducing the risk have been evaluated considering the following criteria:

- *Effectiveness* – Measures must be targeted at those significant hazardous effects and routes of exposure where risks that need to be limited have been identified by the risk assessment; and must be capable of reducing the risks within and over a reasonable period of time;
- *Practicality* – Measures should be implementable, enforceable and as simple as possible to manage (such that smaller enterprises are able to comply);
- *Economic impact* – This should include the impact of the measures on producers, processors, users and other parties; and
- *Monitorability* – Monitoring possibilities should be available to allow the success of the risk reduction to be assessed.

It is of note that various risk management actions are expected to arise as a result of the recent classification of MCCPs according to Directive 67/548/EEC (see Sections 2.2 and 4.6).

Sections 5.4 to 5.7 provide a general summary of the performance of the possible measures against the key criteria of effectiveness, practicality, economic impact and monitorability. Section 5.8 then provides a consideration of the advantages and drawbacks of each of the measures, including quantitative information on costs of controls where appropriate.

Controlling emissions through legislation

Effectiveness

Control of emissions through inclusion of MCCPs as a priority substance or priority hazardous substance under the Water Framework Directive could potentially ensure that all risks to the environment are adequately controlled (i.e. to a level where the PEC/PNEC ratios are below 1). The legislative framework now exists for the Commission to propose water quality standards and emission controls for these substances and such standards and controls could potentially be designed, based on the results of the risk assessment for example, to ensure that emissions are controlled to adequately limit the risks.

If a Community-wide EQS were to be established for MCCPs, Member States would be required to develop measures to ensure that the EQS is met (the deadline for the existing priority substances is 2015; that for any new priority substances would be expected to be later, though measures could start being implemented sooner).

Whilst there are some reasons why derogations or extensions to timescales could be applied under the WFD (e.g. due to disproportionate costs or technical infeasibility), controlling emissions rather than replacing MCCPs with an alternative has the advantage that the risks could be controlled[55] while not directly leading to any additional risks associated with the use of substitutes. This is particularly relevant given environmental hazards associated with some alternatives and the unknown properties associated with several others.

However, it is recognised that, if MCCPs are included as a priority substance under the WFD, whilst substitution of MCCPs with alternatives would not be required, some companies might decide to undertake substitution on commercial grounds. Requiring an EQS to be met would also have the implication of allowing those installations that lead to very low emissions compared to those in the risk reduction strategy to continue operating and using MCCPs without unduly penalising them (since the local exposures associated with these installations are likely to be sufficient to ensure that the PEC does not exceed the PNEC value).

[55] Notwithstanding any potential risks due to the possible PBT properties of MCCPs.

If MCCPs were a priority hazardous substance under the WFD, in addition to achieving an EQS, a cessation or phasing out of discharges, emissions and losses would need to be achieved a timescale that would be set in the legislation.

The timetable for achieving the reductions 'must not exceed 20 years', but could be significantly less than this, if specified by the Commission. However, it may take some years before controls could be implemented, given that MCCPs would first need to be included on the priority list and then appropriate controls would need to be recommended and implemented.

One suggestion of the steering group for this project was to examine the potential for wider controls on organohalogen compounds as a group to be implemented through the water framework directive (rather than controls specific to MCCPs). This could potentially have the advantage of not leading to more widespread 'black listing' of MCCPs that, it has been suggested, might result from inclusion on such EU-wide lists. However, upon examination of the current list of priority substances under the directive, 21 of the 33 substances or groups of substances listed are specific organohalogen compounds for which specific controls will be introduced. Given the diversity of organohalogen compounds, it is considered that further controls on organohalogens in general would not be sufficient to adequately address the risks associated with MCCPs and that the effectiveness of such a measure would be considerably less than targeting controls at MCCPs specifically. It should be noted that there is already a general requirement for Member States with regard to pollution by organohalogen compounds (as detailed in Section 3.5).

This measure would be capable of targeting the risks identified for the aquatic environment (surface water, sediment) and secondary poisoning via the fish-based food chain as it would allow an EQS to be set at a level that is protective for the water environment, taking into account these endpoints.

In relation to targeting risks for the terrestrial environment, including secondary poisoning via the earthworm-based food chain, this measure could also be expected to reduce the risks because:

- For all uses, the PEC/PNEC ratios for surface water or sediment are higher than those for the terrestrial environment and secondary poisoning.
- If the measures taken by those installations leading to a PEC/PNEC ratio greater than 1 reduce emissions (e.g. through reducing releases to sewer) to a level where the PEC/PNEC ratio for both surface water and sediment is less than one, there will be a corresponding reduction in the PEC/PNEC ratios for the terrestrial endpoints (because the quantity of MCCPs entering sewage treatment works would be lower and hence the quantity applied in sewage sludge will also be proportionately lower[56]);

[56] The main contributor to the identified risks for the terrestrial compartment and secondary poisoning via the earthworm-based route is the spreading of sewage sludge on land.

- Thus, the measures taken to address the risks for the water environment could also target the other endpoints sufficiently to reduce all of the PEC/PNEC ratios to below 1;
- However, it is recognised that, if the only measures taken to meet any EQS for MCCPs are to increase retention in sewage treatment works, there could be a greater level of MCCPs applied to land in sludge. This could be avoided by setting limits on the quantities/concentrations of MCCPs emitted to sewer by companies using MCCPs[57].

Practicality

Through the Water Framework Directive, there is a mechanism by which new substances could be included on the priority list. Procedures for enforcement and implementation of measures on specific priority substances are still in the process of development within the Member States.

The approach being taken in relation to priority substances is generally to set EQSs rather than Community-wide emission limit values. This approach allows the main sources of priority substances to be targeted as a basis for ensuring compliance with the EQSs, though the actual level of compliance achieved will be dependent upon the approaches taken by the Member States, including mechanisms for enforcement.
In legislative terms, therefore, a mechanism already exists for controlling releases and environmental (water) concentrations.

In some cases, where there are large numbers of installations potentially contributing to releases of MCCPs (e.g. within a specific river basin), it could be logistically difficult to enforce controls. For example, in relation to use in metalworking fluids, there were estimated to be 153,000[58] companies using metalworking fluids in just five European Countries in 1997 (RPA, 1997). Similarly, in relation to wastewater treatment works (where emissions of MCCPs may also occur when discharges are to sewer), there are estimated to be 11,300 plants in France alone (European Commission, 2001a).
In addition, several of the companies providing information for this report have indicated that legislation to control emissions would be a suitable measure from their perspective (see Appendix B).

Economic Impact

There would be two key areas where costs would be borne if MCCPs were included on the list of priority substances under the Water Framework Directive: Firstly, there would be costs to the authorities in determining and enforcing appropriate controls on emissions. It has not been possible to quantify these costs.

Secondly, there would be costs to the industry sectors concerned in relation to the introduction of emissions controls, including potentially on the water industry. In relation to diffuse sources of MCCPs, these would potentially be disproportionately

[57] In the UK, this could be done through discharge consents.
[58] 50,000 in Germany, 50,000 in the UK, 30,000 in Italy, 15,000 in the Netherlands 8,000 in Belgium.

costly to control; however, for the uses where a need for limiting the risks is identified on the basis of the PEC/PNEC ratios, the predicted concentrations relate mainly to releases from installations at the local level.

The approach adopted in this report for estimation of the costs is based on the assumption that techniques to introduce/ensure emissions controls would have the same costs for business, irrespective of the legislative means by which controls are introduced (Water Framework Directive, IPPC, etc.).

For production of MCCPs, information has been provided on the potential costs of introducing additional controls:

- One company has already spent £50m (€80m) on an 'environmental improvement plant' for its entire site, achieving a 90% reduction on total organochlorine emissions. Based on the results of the risk assessment, it is expected that this should have already reduced all of the PEC/PNEC ratios to below unity. The same company also indicated that an additional carbon filter bed would cost around £100k (€140k); and
- Another company has indicated that double walled storage tanks and exhaust disposal for drum filling could be introduced at a cost of €500k (capital costs).

Additional information is provided in Appendix B to this report.
In general, suitable techniques for the control of emissions of substances such as MCCPs from production sites include use of adsorption by granulated activated carbon or hydrogen peroxide plus UV light[59]. Typical total annualised costs for both of these techniques are around €200,000 per year (European Commission, 2003b).

However, there might also be significant costs associated with monitoring of emissions: one manufacturer has indicated an annual monitoring cost of £10,000 for weekly monitoring, although actual costs would be expected to be significantly lower given that a lower frequency might be expected for those firms using MCCPs (rather than the producers).

This option would allow greater flexibility to companies using MCCPs than a prohibition on use: companies could choose to substitute MCCPs where this is financially preferable to introducing additional abatement measures. In addition, sites where emissions are already adequately controlled would not incur any additional costs, except in relation to demonstrating that controls are already in place.

Table 5.12 summarises the estimated costs for each sector for introduction of techniques to control emissions to the environment. However, the final choice of techniques would need to be tailored to meet the environmental quality standards (or emission limit values under IPPC) appropriate for the reduction of risks associated with MCCPs to a level where the PEC/PNEC ratios are below 1.

[59] These techniques are considered to be suitable for organic chemicals - such as highly chlorinated compounds - that are difficult to biodegrade (and as such are expected to be applicable to MCCPs).

Table 5.12 Indicative costs of emissions controls for industry sectors

Sector	Indicative Costs
Production [1]	Most companies expected to have already reduced emissions. However, assuming controls required at one EU-based company, costs could be around €500,000 (or around €60,000 annualised costs at a 3.5% discount rate and assuming a 10 year investment period).
Polyvinyl chloride (PVC)	Assumed that risks could be limited by (a) ensuring no drains present in raw materials handling, mixing and usage areas; and (b) ensuring thermal oxidation of exhaust gases to prevent re-settling at a cost of perhaps €0.8 to €2.5 million total annualised costs (see Appendix B).
Metal working/cutting	Total continental release up to 1,250 tonnes of MCCP per year (see Section 2). For disposal of neat oils (c. 350 tonnes), disposal costs estimated at £150 (€225) per tonne or around €80,000 per year. For emulsifiable fluids (c. 900 tonnes), MCCPs are at a concentration of around 0.25% (25kg in 10,000 litres). Thus, the total mass that would need to be diverted would be around 360,000 tonnes, with an associated cost estimated at around €80 million per year but borne over many companies (e.g. if the cost is shared by around 100,000 companies, the cost would be around €800 per company per year. Actual costs will be much lower as most companies will have recovery/recycling/disposal procedures in place already. These estimates are based on extrapolation from worst case emissions estimates.
Rubber/polymers (other than PVC)	No information available from companies on costs. Suggested techniques include cooling water circuits, air filtering, addition treatment of waste water where parts that come in contact with MCCPs are cleaned. Assuming 20 companies using MCCPs for these applications (based on extrapolation from questionnaire return), of which 50% would need e.g. treatment of exhaust gases, annualised costs could be around €100-200,000 by analogy with approach for PVC.
Leather fat liquors	Costs of possible emissions reductions unknown.
Carbonless copy paper [2]	Controls would have to be introduced at paper recycling facilities. In order to ensure all emissions are controlled, secondary treatment could be installed at all facilities without this in place at an estimated annualised cost of €137 million. However, as indicated in Appendix B, the costs could be significantly lower than this, given that sites recycling paper are more likely to have secondary treatment in place than those only producing paper. Nonetheless, this measure is not considered to be appropriate or proportionate for addressing the mainly legacy-related risks associated with this application. Whether such controls should be introduced due to wider concerns on emissions from these sites is not considered in this report.

[1] The updated work on the risk assessment indicates that there is no longer an identified need to limit the risks for production of MCCPs.

[2] The updated work on the risk assessment indicates that there is no longer use of MCCPs in carbonless copy paper.

Monitorability

In addition to the aforementioned issues related to practicality of monitoring emissions, several of the consultees for this project have indicated that there is no standardised methodology for measurement of chlorinated paraffins in aqueous effluents. One method has been developed in the UK (LGC, 2003), although it is understood that it has not yet been possible to validate the method with other laboratories. Several other methods are available although there is not yet considered to be sufficient uniformity in the results produced.

Therefore, in order for the success of this measure to be effectively monitored, it will be necessary to ensure that a suitable analytical monitoring method is developed and agreed upon. For sectors where there are no other sources of chlorine in effluent, it may be possible to measure concentrations of adsorbable organic halogen (AOX) as a surrogate for measuring MCCPs. Standard analytical procedures exist for undertaking measurements of AOX[60].

It should also be noted that the specific measures to implement this option would need to be developed at a Member State level.

Voluntary commitment to control emissions

Effectiveness

In theory, a voluntary commitment to control emissions to specified levels could have the same level of effectiveness as legislation to control emissions. It would, however, require the majority of companies involved in production and use of MCCPs to participate (see below).

Practicality

The success of any such agreement would depend upon there being sufficient coverage of the companies involved to ensure that emissions are adequately controlled. For production of MCCPs, companies have expressed a willingness to participate in such an agreement and one of the key criteria for such agreements, namely that signatories should represent the majority of the sector (see Section 4). However, it is of note that the risk assessment now concludes that there is no need to limit the risks associated with production of MCCPs based on the PEC/PNEC ratios.

However, for certain other uses – most notably use in metalworking fluids – there is a large number of small sized companies involved and it would be logistically very difficult to obtain sufficient coverage of the sector. By analogy to the UK manufacturing sector as a whole, it might be expected that over 95% of the companies involved would be classified as small companies (with fewer than 50 employees) and around 85% would be companies with fewer than 10 employees[61] (although it should be borne in mind that larger companies will frequently use significantly larger quantities of MCCPs and thus, whilst there may be a large number of companies using MCCPs, a small number of larger companies may constitute a greater proportion of use).
In several cases, the risk assessment is based on assumptions regarding realistic worst-case emissions scenarios at sites using large quantities of MCCPs. For smaller

[60] Whilst measuring AOX does not provide information on the specific chemical species, if MCCPs are the only source of chlorine, this method would give an accurate measure of the concentration of MCCPs, provided that the chlorine content of the MCCPs is known. For the PVC industry, this method is not likely to be suitable for determining the concentration of MCCPs, due to other sources of chlorine in effluent.

[61] Based on data from the Small Business Service (2004), there were around 290,000 companies in the manufacturing sector with fewer than 50 employees and 260,000 with fewer than 10, out of a total of around 300,000 companies.

companies, due to the quantities used, the risks will not necessarily be unacceptable. Therefore, a voluntary agreement might not need to cover all companies in order to adequately limit the risks; just the largest ones. Overall, particularly for the metalworking sector where there is a large number of small companies, a voluntary commitment to control emissions is unlikely to achieve sufficient coverage to adequately limit the risks.

Economic Impact

As compared to legislation to reduce emissions, it would be expected that costs to the authorities would be lower, since there would be fewer monitoring and enforcement requirements. However, there would be expected to be costs associated with ensuring that the voluntary agreement is complied with (even if all monitoring is undertaken by industry).

In relation to the costs for industry, as with legislation to control emissions, there could be significant costs in reducing emissions for those installations where emissions are currently sufficient for the PEC/PNEC ratios to be exceeded. These would be expected to be of the same order as for a legislative approach. Again, this type of approach would have the advantage that it would target those installations that contribute to the highest concentrations in the environment whilst not imposing significant cost burdens upon those with relatively low current emissions.

Monitorability

It would be relatively simple to monitor compliance with emissions controls for sectors where there are relatively few companies involved (e.g. production of MCCPs). However, as discussed in relation to the practicality of this option, the large numbers of companies involved in some sectors (e.g. use of metalworking fluids) would make monitoring problematic.

In addition, as with potential legislation to reduce emissions, a standardised method for monitoring of aqueous effluents would need to be developed.

Restricting marketing and use through legislation

Effectiveness

Restricting some or all uses of MCCPs would eliminate any future environmental inputs and thus reduce the impacts upon the environment over time. However, there would be an increase in environmental risks – and risks to health – associated with use of any substitutes[62] that would offset the reduction in risk to an extent depending upon the substitute and application in question. As detailed earlier in this section, many of the potential replacements for MCCPs in metalworking fluids have significantly less data available concerning environmental hazards and risks and there would thus be a

[62] An increase in the use of substitutes (and reduced use of MCCPs) is likely for any risk reduction measure since the additional effort/investment required to implement the measure may be sufficient for some companies to abandon use of MCCPs, even if not legally required to do so.

considerable level of uncertainty regarding the overall change in risks. In addition, substitution of MCCPs in certain metalworking applications is particularly problematic, especially for applications such as deep drawing, punching, extrusion and pilgering. For several of the other uses, substitutes are more readily available and indeed these have been introduced in applications such as carbonless copy paper and leather processing, as well as less arduous metalworking operations. Substitutes also appear to be readily available for use in PVC, although there remain concerns regarding the change in environmental risks that would be expected, particularly in relation to substances that would be needed for flame resistant applications.

This Directive (and the replacement process for restrictions under REACH) provides a flexible means of introducing restrictions. It is possible for restrictions to be introduced for some applications while allowing derogations for certain uses where risks to the environment can be adequately controlled (e.g. under contained conditions) or where there are no suitable alternatives available.

The application of marketing and use restrictions with such derogations could potentially allow the majority of releases to the environment to be addressed while allowing use of MCCPs to continue in those applications where there are no technically feasible alternatives. However, the drawbacks associated with the use of certain substitute, some of which may not have improved environmental hazards/risks, would not necessarily be removed.

It is of note that, for several uses of MCCPs, potentially significant releases have been identified (in the risk assessment) to occur during the service life of products, particularly for paints, adhesives and sealants (where no need for limiting the risks is identified based on PEC/PNEC ratios) and also for use in PVC. In addition, releases may occur through waste remaining in the environment. Whilst no quantification of the environmental risks from these uses is available, it is concluded – taking into account comments from various Member States – that the concern for such releases could be significantly elevated if MCCPs are determined to have PBT characteristics. Wider restrictions on marketing and use could, therefore, be more appropriate *if PBT properties are confirmed.*

Practicality

Restrictions on the marketing and use of MCCPs would be relatively simple to implement as suitable measures have been developed under Directive 76/769/EEC and under REACH. However, it could potentially be problematic to enforce in relation to imports from outside the EU, given that there is currently no available means of identifying MCCPs based on customs codes.

However, in terms of implementation, particularly for metalworking fluids, it is likely to be impossible in some cases to substitute MCCPs and retain the same degree of technical efficacy (see Appendix B for details). As mentioned above, such uses could potentially be subject to derogations/exemptions. However, there is insufficient information currently available to indicate all of the uses where substitutes are not technically suitable (initial indications for metalworking are that these include deep drawing, punching, extrusion and pilgering[63], though there may well be other applications).

For other uses of MCCPs, companies could generally implement substitution of MCCPs, although there would be significant development time required in certain applications.

Economic impact

The direct economic impacts of marketing and use restrictions would relate to the need to reformulate products, modify production processes and purchase alternative raw materials (MCCPs are primarily used in several applications for reasons of cost).
In cases where equipment currently used could not be used instead to produce and or use alternatives to MCCPs, there would also be costs associated with the lost value of the equipment, if this becomes redundant before the end of its useful life. Obviously the costs associated with this latter point would be reduced if the time limit set for any marketing and use restrictions were sufficient to allow a move to alternatives in line with existing investment cycles within the sectors and companies concerned.
Table 5.13 provides a summary of information available through the risks reduction strategy regarding the costs of potential substitution of MCCPs by downstream users.

[63] German experts also indicated that uses where no suitable alternatives exist include those using extreme pressure and especially ductile or hard materials.

Table 5.13 Potential costs to users of substituting MCCPs

Sector	One-off development & capital costs	Ongoing costs
PVC	None assumed for replacement with phthalates for wallcoverings. None assumed for 'other' uses where flame retardancy not an issue. Where flame retardancy is required, assuming €50k per 100t of use for 50% of use (15,000 tonnes). Gives one-off costs of around €15 million or €3.4 million per year (assuming 5 year investment period and 3.5% discount rate).	For 30,700 tonnes used in EU, approx. €10m per year based on substitution of MCCPs (c. €500/t) with DINP (c. €800/t). Further costs would be expected where additional flame retardancy is required and total costs could be around €30 million per year (Appendix B).
Metalworking	One company indicates spending €3.5m (by 2003) with no suitable alternatives found thus far for certain key applications (LCCPs are also used by this company and have been historically). Additional information made available in 2008 suggests that key applications where substitution is difficult *for this company* are drawing of pipes and pilgering alloys. One large car producer mentioned in a review for the German Government indicates costs of several million DM (and hence Euro). The precise cost of CP substitution could not be estimated. However, the process of substitution was part of an overall process innovation (of which CP substitution occurred as a desired side effect), with net benefits achieved in cost and environmental and human health (Stolzenberg, 2000). There is a general trend across many companies towards seeking alternatives to chlorinated paraffins.	Unknown.
Paints	€2k - €75k per company (depending upon number of formulations and time taken). Assume €20k per company and average 25 t/yr usage, gives an estimated 100 companies so €2 million one-off costs (€440,000 per year based on same assumptions as for PVC).	€800/t increase for LCCPs = around €1-2 million per year for all paint use [1] Increased cost of €100,000 for use of terphenyls for 35 tonnes use - equates to around €2850 per tonne more or around €3350 per tonne total.
Rubber and other polymers	€6 million for redeveloping and testing in EU rubber industry.	€375k per year increase in raw material cost for replacement with LCCPs
Leather fat liquors	No significant redevelopment costs expected.	Substitution with LCCPs likely to cost around €130,000 per year (Appendix B). Also, by analogy with SCCPs, increased costs of €370 per tonne could be expected, or around €500,000/yr for all fatliquors produced in the EU (€150,000/yr for those used in the EU).
Carbonless copy paper	Unknown but not expected to be significant as use has decreased almost to zero	Unknown but not expected to be significant as use has decreased almost to zero
Total	> €23 million	> €32 million per year

[1] Sealants not considered as no need for risk reduction has been identified. Note that the latest version of the risk assessment also now indicates no need for limiting the risks for paints.

Costs to the producers of MCCPs associated with the loss of revenue from these products are estimated at around €45 million per year based on total production (as compared to EU sales worth around €28 million per year), although there would be an increase in revenue for the producers of the substitutes.

The costs of marketing and use restrictions could be lower than those indicated above if the restrictions introduced did not cover, through derogations, applications where the alternatives are either not currently technically suitable or where their use would pose disproportionate costs to the industry sectors concerned (or indeed where uses are already adequately controlled). However, it should be noted that the costs above are minimum values for some of the sectors, particularly metalworking.

However, several consultees have indicated that some plants could potentially have to shut down in the event that suitable replacements could not be found. This appears to be particularly relevant in relation to production of MCCPs and for use of metalworking fluids. It has also been suggested that the existing decline in some industries may be exacerbated by any requirement not to use MCCPs through closure of plants. For example, in the UK, there was a contraction in both the iron and steel and non-ferrous metals sectors to around 73% of 1990 levels by 2003 (DTI, 2004).

Marketing and use restrictions would also impose costs upon the authorities in terms of developing legislation and also in regulating/enforcing that legislation.

Monitorability

It is considered that suitable mechanisms for monitoring of the success of any marketing and use restrictions are available for measures introduced under Directive 76/769/EEC and now under REACH. Sales data from suppliers of MCCPs could potentially be utilised to ensure that no sales were occurring to prohibited uses.

However, since a significant proportion of sales occur through distributors, it may be difficult to monitor whether sales are occurring to prohibited uses from such companies. In addition, as detailed in Section 1 of this report, there is a large number of different CAS Numbers under which MCCPs may be classed. Identification of which substances are being sold and imported/exported could thus be very difficult to monitor in practice. In addition, there is no single customs code under which MCCPs are included so it would potentially be very problematic to monitor imports and sales to particular sectors.

Restricting uses through a voluntary commitment

Effectiveness

Restriction of certain uses through a voluntary commitment would be effective in ensuring that the risks associated with MCCPs are removed for those applications. However, as with marketing and use restrictions, they would not ensure that any risks associated with substitutes would be adequately controlled.

This measure is likely to be most simple to implement where there already exists very minimal usage of MCCPs, such as in carbonless copy paper, though the environmental benefits would be greatest in sectors where emissions are highest.

Practicality

As with a voluntary commitment to reduce emissions, there would be issues relating to implementation and enforcement for sectors where there are a large number of companies involved, such as the metalworking industry. For certain other sectors, the measure would be more simple to implement: for example in relation to carbonless copy paper, over 95% of the EU producers are members of the AEMCP which already has a voluntary commitment that requires that MCCPs should not be used for this application (and indeed MCCPs do not now appear to be used in this application). Furthermore, some of the producers of MCCPs have indicated that they will not promote this option.

Economic Impact

Since voluntary cessation of certain uses of MCCPs would require substitution with alternative products, the economic impacts would be expected to be similar to those for marketing and use restrictions. The economic impacts upon industry could be reduced as compared to legislative restrictions, however, if the timescales for (and potentially uses targeted by) restrictions were made sufficient to allow more substitution to occur in line with industry investment cycles.

Monitorability

This option could potentially be monitored through sales data on MCCPs, as for marketing and use restrictions. However, the same concerns as highlighted for marketing and use restrictions also apply here (the large number of CAS Numbers used to describe chlorinated paraffins and the lack of a specific customs code for monitoring of imports).

Summary of advantages and drawbacks of measures

Introduction

This section provides a summary of the relative advantages and drawbacks of each of the risk reduction options for each of the sectors under consideration. The main points are summarised in tabular form based on the information in Sections 5.3 to 5.7, as well as the sector-specific information in Appendix B.

Production of MCCPs

Based on the most recent results of the risk assessment and the information presented in Section 2 of this report, the level of risk for production sites does not need to be limited in relation to the identified PEC/PNEC ratios.

However, if risk reduction measures are introduced to address the downstream uses of MCCPs, there would also be implications for the producers of MCCPs (for example through reduced demand). There would also be implications if any measures were to be taken on a precautionary basis to address the possible PBT characteristics of MCCPs. Table 5.14 provides a summary of the advantages and drawbacks of the possible measures.

Table 5.14 Advantages and drawbacks of possible measures for MCCP production

Option	Advantages	Drawbacks
1) Limiting emissions through legislation	Would not be expected to affect producers since PEC/PNEC values are already below 1. Also, would address risks of MCCPs without introducing potential new risks from substitutes.	Would require costs in development of legislation (costs for development of EQSs, etc.).
2) Limiting emissions through voluntary agreement	Would reduce risks of MCCPs without introducing potential new risks from substitutes. Compared with (1) would not require expenditure by authorities in implementing legislation.	Less certainty regarding outcome if failure to reach agreement.
3) Restricting marketing and use through legislation	Would eliminate environmental risks associated with MCCPs. Possible advantage to EU producers of alternatives if located inside EU.	If all uses restricted, market worth around €45 million per year (including extra-EU exports) would be lost and remaining cost of production facilities would be lost. New risks associated with emissions of substitutes.
4) Restricting Uses Through a Voluntary Commitment	Only advantage in relation to producers would be a reduction in overall emissions from production (advantages for other sectors considered elsewhere)	Loss of part of market for producers.

Note that there is no longer an identified need for limiting the risks from production based on the PEC/PNEC ratios.

Given that the latest version of the risk assessment no longer indicates a need for limiting the risks for production of MCCPs, it is concluded that no further measures are required to limit the risks from production facilities.

Notwithstanding this, the producers of MCCPs will have a role under REACH in ensuring that the risks associated with MCCPs are adequately controlled throughout the supply chain.

It is of note that the timescale for implementation of the IPPC Directive has now passed (October 2007). All of the installations producing MCCPs could be expected to have emission limit values in place to limit releases to the environment. There may be a role for the conclusions of the risk assessment and the risk reduction strategy to be taken into account in ensuring that these emission limit values are sufficiently protective to ensure that the releases associated with production of MCCPs (e.g. for any new installations) will not pose an unacceptable level of risk to the environment.

PVC

Table 5.15 provides a summary of the advantages and drawbacks of each of the possible risk reduction options in relation to use in PVC products.

Table 5.15 Advantages and drawbacks of possible measures for use in PVC

Option	Advantages	Drawbacks
1) Limiting emissions through legislation	Many sites already expected to have adequate controls in place (e.g. no drains in key site areas, fume abatement equipment such as thermal oxidisers, etc.), so only those needing additional controls would need to install abatement equipment. Does not introduce risks associated with substitutes (although some substitutes e.g. DINP, DIDP expected to be of lower risk to environment). Could control all risks (including terrestrial and earthworm secondary poisoning route as well as aquatic environment) provided that steps are taken to control risks at source.	Indicative costs of controls for industry estimated at €0.8 to €2.5 million per year (e.g. introduction of thermal oxidisers). However, significant uncertainty given that numbers with adequate controls in place are unknown. Existing legislation such as IPPC Directive will not apply to many sites so Water Framework Directive likely to be more applicable. Costs for authorities with introducing legislation (e.g. controls under Water Framework Directive). Monitoring costs for industry/regulators and lack of a fully developed analytical method.
2) Limiting emissions through voluntary agreement	Same advantages as (1) and also likely to be significantly lower costs for authorities. Companies contacted for this work (c. 10% of MCCP use for PVC) support this approach.	Uncertainty regarding extent of sectoral coverage achievable and total number of companies unknown.
3) Restricting marketing and use through legislation	Eliminates contribution of PVC to environmental risks associated with MCCPs. Derogations could be applied for uses without suitable alternatives so as to avoid some of the drawbacks. Would eliminate concern related to releases from PVC during service life; this is especially significant if PBT properties are determined.	Possible total annualised costs of around €33.4 million per year based on substitution with phthalates and flame retardant additives where appropriate. Potential risks associated with substitutes (particularly where flame retardancy is required) – does not guarantee overall reduction in risks and may be significant risks associated with some alternatives. Penalises installations not leading to unacceptable risks to the environment (PEC/PNEC ratio <1); controls understood to be in place in many installations in practice.
4) Restricting Uses Through a Voluntary Commitment	Eliminates contribution of PVC to environmental risks associated with MCCPs.	Costs to industry similar to (3), although timeframe could be tailored to suit phase-out. Lower costs for authorities than (3). Significant market loss for producers of MCCPs. Unlikely to gain support based on information provided for this risk reduction strategy.

The possible cost of substituting MCCPs in PVC is estimated at around €33 million per year. The increase in ongoing substitution costs is approximately a 150% increase in raw material costs on average, although the costs where substitution with phthalates alone is undertaken could represent only a 60% increase in costs. Reformulation and substitution costs could be a significant proportion of companies' turnover, particularly where the fire resistant properties of MCCPs are of relevance (e.g. flooring).
The costs of limiting emissions to environment are estimated to be significantly lower than those for substitution of MCCPs and such an approach should be capable of

reducing emissions to a level where PEC/PNEC ratios are below 1 across all relevant companies (given that a proportion are already expected to control risks adequately), provided that there is adequate monitoring of emissions.

For use of MCCPs in PVC, it is considered that the approach representing the most appropriate balance of advantages and drawbacks would be to ensure that emissions are controlled to an adequate level. Companies where emissions are already well controlled would need to undertake monitoring of emissions to ensure compliance with appropriate limits. For sites where emissions are likely to pose an unacceptable risk to the environment, additional abatement equipment would be required. It is considered that the cost of introducing such abatement equipment would be significantly less than for substitution of MCCPs overall. However, for companies where the costs of substitution are less than that of installing abatement equipment, it is likely that they would undertake substitution.

The most appropriate means of ensuring compliance with suitable emission limits would be through including MCCPs as a priority substance under the Water Framework Directive (this could target all major sources of emissions – see Section 5.4). Whilst aimed at targeting releases to or via the aquatic environment, if controls on emissions are introduced at source, this could also be sufficient to adequately limit the PEC/PNEC ratios associated with the terrestrial compartment and secondary poisoning via the earthworm-based route.

In addition, control of emissions from sites covered by the IPPC regime could be introduced through requirements specific to MCCPs. Furthermore, control under IPPC would also allow the effectiveness of the risk reduction measures to be assessed by a reduction in the quantities reported for the national and European pollution inventories[64].

Given that this process may take some time to implement (initial work on the proposed second list of priority substances is underway), it may also be considered worthwhile investigating the potential for a negotiated agreement with industry to ensure emissions are limited to an appropriate level. Most of the companies consulted for this risk reduction strategy have indicated that they favour this approach to achieving a reduction in risks and so it is likely that agreement could be reached on such an approach (provided an appropriate monitoring method is in place). However, given the limited time remaining for agreement to proposals for risk reduction measures under ESR, it is recognised that the Commission is focusing primarily upon specific regulatory outcomes that the Commission can take (under existing Community legislation). As such, it may be appropriate to not consider this option further at the present time in the context of gaining agreement to the risk reduction strategy under ESR.
It is of note that, for several uses of MCCPs, potentially significant releases have been identified (in the risk assessment) to occur during the service life of products, particularly for paints, adhesives and sealants (where no need for limiting the risks is

[64] Whilst MCCPs have been included on the UK ‘Pollution Inventory’ since 2002, only SCCPs are currently included on the European Pollutant Emission Register.

identified based on PEC/PNEC ratios) but also for use in PVC. In addition, releases may occur through waste remaining in the environment. Whilst no quantification of the environmental risks from these uses is available, it is concluded – taking into account comments from various Member States – that the concern for such releases could be significantly elevated if MCCPs are determined to have PBT characteristics. Wider restrictions on marketing and use could, therefore, be more appropriate *if PBT properties are confirmed*.

Metalworking

Table 5.16 provides a summary of the advantages and drawbacks of the possible measures in relation to controlling the risks associated with use of MCCPs in metalworking fluids.

Table 5.16 Advantages and drawbacks of options for use in metalworking fluids

Option	Advantages	Drawbacks
1) Limiting emissions through legislation	Could potentially reduce risks associated with MCCPs without directly introducing risks associated with possible substitutes [1]. Does not introduce risks associated with substitutes. Could control all risks (including terrestrial and earthworm secondary poisoning route as well as aquatic environment) provided that steps are taken to control risks at source.	Potentially time-consuming to implement and could be difficult to target the large number of smaller companies that are likely to use MCCPs. Will be cost implications for companies in complying with the legislation where emissions need to be reduced.
2) Limiting emissions through voluntary agreement	Lower costs for industry and authorities than (1) or (3).	Likely to be highly impractical to obtain significant participation amongst end-users (many companies using MCCPs, many of which are small companies and not represented through trade associations).
3) Restricting marketing and use through legislation	Would remove risks to the environment associated with MCCPs. Derogations could be applied for uses without suitable alternatives so as to avoid some of the drawbacks.	Costs for reformulation of metalworking fluids expected to be significant (but part of an ongoing process). Where substitutes not available, costs may be very significant and may lead to inability to manufacture certain products (e.g. one company has spent over €3.5 million to date with no substitute found). Several substitutes identified may not pose lower risks to the environment (high uncertainty for some and indications of potential concern for others). Some of these drawbacks could be removed if derogations were in place for applications with no suitable alternatives.
4) Restricting Uses Through a Voluntary Commitment	Has the potential to remove risks to the environment. Lower costs for industry and authorities than (1) or (3).	Several substitutes identified may not pose lower risks to the environment (high uncertainty). Likely to be highly impractical to obtain significant participation amongst end-users.

[1] Although there would probably be some substitution where the most cost-effective solution for companies is to substitute MCCPs rather than introduce additional emissions controls.

There is a relatively large number of companies involved in metalworking operations, many of which are not generally represented through relevant trade associations. Therefore, it is considered that gaining an agreement to reducing emissions or to restrict certain uses *through a voluntary agreement with the users of metalworking fluids* is likely to be inappropriate. It may be more appropriate, however, to target the formulators of MCCPs for this application because greater numbers have links within supply chains and trade associations. However, it was not possible to identify how this could be achieved in concrete terms for this risk reduction strategy.

Legislation to control emissions (through prioritisation under the Water Framework Directive and also ensuring controls at larger facilities through the IPPC regime) could be used to target the most significant sources of MCCPs in the environment resulting from metalworking fluids. The WFD approach may raise issues of practicality in targeting the large number of small companies at which releases may occur. However, specific installations could be targeted on the basis of monitoring to identify those areas with high concentrations as a basis for targeting specific installations (either discharging directly to water or through limiting their emissions to sewer).

In order to ensure that the release with the highest calculated risk characterisation ratio for this sector – intermittent release of emulsifiable metalworking fluids – is adequately controlled, the most appropriate risk reduction option is considered to ensure that legislation is in place to ensure that such disposal is not permitted. As discussed in Section 3.8, it is concluded that such activities should historically have been controlled under legislation such as the Waste Oils Directive (75/439/EEC) which essentially places a requirement preventing discharge of MCCP-based metalworking fluids to drain[65]; however, this practice cannot be ruled out given that the Directive allows for discharge if an appropriate permit is in place. The recently adopted Directive on waste should provide the means to address the risks associated with such releases, though this will be dependent upon the approaches to be adopted by the Member States.

If legislation to control emissions through the water framework directive and the IPPC regime, along with improved legislation (and enforcement) on the requirements on waste oils are introduced, it is considered likely that the highest concentrations in the environment could be significantly reduced. For example, if the risks associated with intermittent release of metalworking fluids are addressed through the latter, there should no longer be a need for limiting the risks associated with emulsifiable metalworking fluids (highest PEC/PNEC ratio would be 0.4 and releases from waste treatment facilities should give PEC/PNEC ratios less than 1, as detailed in Section 2 of this report, based on the environmental risk assessment).

The highest remaining PEC/PNEC ratio for use of oil-based metalworking fluids would be 1.8 (for large facilities which could potentially be controlled under the IPPC regime; that for small facilities is 1.7) and the highest value for formulation would be 4.2. It is considered likely that the sources contributing to these releases could, to a large extent, be addressed through controls under the IPPC Directive, the Water Framework Directive and legislation on waste oils. This route may be sufficient to reduce all identified risks to a level where the PEC/PNEC ratios are below 1.

Given that there are potentially significant financial implications of marketing and use restrictions for use in oil-based fluids and because there are no identified substitutes for some applications, it is considered to be inappropriate to restrict the marketing and use of MCCPs in oil-based fluids on the basis of the risks identified on the basis of PEC/PNEC ratios.

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65 Indeed, most sites would not be expected to discharge large quantities of emulsifiable metalworking fluids to drain without first separating out the oil phase. Therefore, the potentially high level of concern for this scenario does not relate to the majority of sites

However, it is acknowledged that significant steps have been taken within the metalworking industry to substitute chlorinated paraffins and also that this use contributes significantly to overall continental emissions of MCCPs (as set out in Section 2). Given the concerns regarding the possible PBT properties identified in the risk assessment, it may be appropriate to consider marketing and use restrictions on a precautionary basis for uses where substitution is feasible[66]. It should be noted that it has not been possible to draw up a definitive list of uses where substitution is not possible. Possible precautionary action is considered below.

In the previous draft of this risk reduction strategy, a possible means of encouraging substitution of MCCPs was identified through industry recommending that MCCPs should be substituted by less dangerous substances[67] where this is technically feasible and not prohibitive in cost terms (e.g. by the trade association representing formulators of metalworking fluids). This has not been considered further in this revised report given that it is not expected to be acceptable to the industry concerned. However, the association representing the producers of MCCPs (CPIA) has indicated that it may be possible to achieve an overall product stewardship-handling programme that is targeted at all additives (rather than MCCPs specifically), particularly the metalworking fluid itself, rather than the MCCPs or any other specific additive.

Paints

The latest version of the risk assessment does not identify a need to limit the risks associated with the use of MCCPs in paints based on the PEC/PNEC ratios. Therefore, the information presented in this section is included for information purposes only as a basis for better understanding the implications of possible measures on this sector.

Table 5.17 provides a summary of the advantages and drawbacks of the possible measures for the use of MCCPs in paints.

[66] Substitution is expected to be possible in some applications but not all, so marketing and use restrictions may place an unacceptable burden upon the industry where substitutes are not available. Such restrictions could lead to a loss of production in the EU where suitable substitutes are not currently available.

[67] Such as those not classified as dangerous to the environment under Directive 67/548/EEC.

Table 5.17 Advantages and drawbacks of possible measures for use in paints

Option	Advantages	Drawbacks
1) Limiting emissions through legislation	Significant reductions compared to the risk assessment already expected through the solvent emissions directive. Emissions could be reduced without introducing new risks associated with possible substitutes. Would not adversely affect companies with low emissions already. Could control all risks (including terrestrial and earthworm secondary poisoning route as well as aquatic environment) provided that steps are taken to control risks at source.	Less practicable where coating takes place outside, etc. Current legislative regime (e.g. solvent emissions directive) relates mainly to emissions to air and so controls specific to emissions to water could not easily be introduced on an industry-specific basis. However, these could be applied through an EQS.
2) Limiting emissions through voluntary agreement	Emissions could be reduced without introducing new risks associated with possible substitutes. Would not adversely affect companies with low emissions already.	Less practicable for industrial application of paints (potentially large number of companies).
3) Restricting marketing and use through legislation	Would eliminate potential concern related to releases from paints during service life; this is considered to be potentially significant if PBT properties are determined.	Possible total annualised costs for substitution of €1.4 to €2.4 million per year, representing 0.01 to 0.02% of turnover of the EU coatings industry or 1 to 2% of the turnover related to these products [1]. Possible environmental risks introduced through use of some alternatives (some identified as dangerous to the environment by consultees). Some companies may be unable to substitute (e.g. in acrylic and chlorinated rubber paints), possibly leading to loss of products or deterioration of quality.
4) Restricting Uses Through a Voluntary Commitment	Potentially less costly for industry than (3) due to flexibility in timeframes, etc. Lower costs to authorities than (3) since no legislation needed.	Potentially difficult to obtain sufficient coverage, particularly for application of paints. Possible environmental risks introduced through use of some alternatives (some identified as dangerous to the environment by consultees).

[1] Based on both annualised capital costs and annual ongoing costs. Total coatings turnover is €16 billion per year, with sales of 5.6 million tonnes (see Section 1). Coatings using MCCPs are estimated at 50,000 tonnes per year, or 1% of total EU sales, representing a sales value of around €140 million per year.

Based on the information provided for this risk reduction strategy (information from six companies, representing nearly a quarter of MCCP use in paints in the EU), it is evident that many companies already have significant abatement techniques in place. The introduction of additional abatement equipment is expected to be partly due to increased requirements for pollution control introduced through the Solvent Emissions Directive. In relation to formulation of paints, techniques used that will tend to mean emissions are lower than those assumed in the risk assessment include:

- Washing equipment with organic solvents (e.g. xylene) which is then recovered;

- Presence of sealed floors/bunds where MCCPs are handled (and the absence of site drains);
- Closed mixing vessels, with filtering of extracted fumes; and
- Collection of site spillages.

If these sites are representative of other paint formulators, it is likely that emissions from paint formulation will already be well controlled through existing legislation.
In relation to industrial application of paints (in applications such as anti-corrosion paints, outdoor wall paints, protective coatings for metal and some underwater epoxy primers), some coating activities are likely to be controlled through legislation such as the Solvent Emissions Directive. However, there may be some cases where industrial application is not controlled in such a manner, although the amounts used per site are likely to mean that the relevant PEC/PNEC ratios are lower than those calculated for the worst case site in the risk assessment.
Given the following factors:

- the relatively high costs associated with substitution of MCCPs in paints (estimated at up to 2% of the turnover related to sales of finished product); and
- the fact that the PEC/PNEC ratios are relatively low.

it is considered that marketing and use restrictions (a ban on use of MCCPs) would be inappropriate for this sector based on the PEC/PNEC ratios. Furthermore, given that there is no longer an identified need to limit the risks based on the PEC/PNEC ratios, it is considered appropriate for no additional measures to be applied specifically to target this sector.

It is of note that, for several uses of MCCPs, potentially significant releases have been identified (in the risk assessment) to occur during the service life of products, particularly for paints, adhesives and sealants (where no need for limiting the risks is identified based on PEC/PNEC ratios) and also for use in PVC. Releases are less significant for rubber and other polymers. In addition, releases may occur through waste remaining in the environment. Whilst no quantification of the environmental risks from these uses is available, it is concluded – taking into account comments from various Member States – that the concern for such releases could be significantly elevated if MCCPs are determined to have PBT characteristics. Wider restrictions on marketing and use could, therefore, be more appropriate *if PBT properties are confirmed*.

Rubber and other polymers

Table 5.18 provides a summary of the advantages and drawbacks of the possible measures for the use of MCCPs in rubber and polymers other than PVC.

Table 5.18 Advantages and drawbacks of options for use in rubber and other polymers

Option	Advantages	Drawbacks
1) Limiting emissions through legislation	Some sites already expected to have adequate controls in place (e.g. where no contact with water), so only those needing additional controls would need to install abatement equipment. Does not introduce risks associated with substitutes. Companies and trade association support this approach since companies could decide whether to introduce emissions abatement or substitute MCCPs. Could control all risks (including terrestrial and earthworm secondary poisoning route as well as aquatic environment) provided that steps are taken to control risks at source.	Costs to industry of reducing emissions and to authorities of introducing controls. Costs to industry unknown though possible techniques identified by industry (e.g. additional treatment of waste water).
2) Limiting emissions through voluntary agreement	Same advantages as (1) and also likely to be significantly lower costs for authorities.	Uncertainty regarding extent of sectoral coverage achievable and total number of companies unknown.
3) Restricting marketing and use through legislation	Eliminates contribution of this sector to environmental risks associated with MCCPs. Would eliminate concern related to releases from rubber/polymers during service life; this is potentially significant if PBT properties are determined (though releases are less significant during service life than for various other applications).	Possible €6 million for redeveloping and testing in EU rubber industry plus €375k per year increase in raw material cost for replacement with LCCPs Potential concern for risks associated with substitutes (particularly where flame retardance is required). Industry believes that this would lead to the closure of companies in this industry with the associated loss of jobs. Costs are significant compared to turnover but insufficient information is available to verify this assertion.
4) Restricting Uses Through a Voluntary Commitment	Eliminates contribution of this sector to environmental risks associated with MCCPs.	Costs to industry similar to (3), although timeframe could be tailored to suit phase-out. Lower costs for authorities than (3). This option is not preferred by the companies and association providing information for this study.

Given the relatively small quantity used in this sector, the contribution to overall environmental inputs is significantly less than for some other sectors (e.g. less than 0.1% of total emissions at the continental level based on the risk assessment; see Section 2). In addition, the highest PEC/PNEC ratio is only 1.23.

Therefore, it is considered that this sector is of significantly lower concern than certain other sectors (e.g. use in leather fat liquors, metalworking). Given the potentially high costs of substituting MCCPs and that the industry association (Blic) and companies favour legislation to control emissions, it is considered that the most appropriate risk reduction strategy would be to:

- Recommend that appropriate emission limits be introduced for production of rubber under the IPPC regime, where compounding and conversion could be covered by the Directive; and
- Introduce controls on discharges, emissions and losses through recommendation that MCCPs be included on the priority list of substances under the Water Framework Directive.

It is of note that, for several uses of MCCPs, potentially significant releases have been identified (in the risk assessment) to occur during the service life of products, particularly for paints, adhesives and sealants (where no need for limiting the risks is identified based on PEC/PNEC ratios) and also for use in PVC. Releases are less significant for rubber and other polymers. In addition, releases may occur through waste remaining in the environment. Whilst no quantification of the environmental risks from these uses is available, it is concluded – taking into account comments from various Member States – that the concern for such releases could be significantly elevated if MCCPs are determined to have PBT characteristics. Wider restrictions on marketing and use could, therefore, be more appropriate *if PBT properties are confirmed*.

Leather fat liquors

As detailed in Section 2, the results of the risk assessment indicate that use of MCCPs in leather fat liquors is one of the areas of greatest concern, with high PEC/PNEC ratios and relatively high levels of emissions as compared to use. In addition, whilst some of the companies involved in leather processing are covered by relevant environmental legislation – notably the IPPC Directive – this will only apply to the larger companies. As detailed in Appendix B, only around ten of the 2,400 companies in Italy are expected to come under the scope of IPPC, that is those with a production capacity of more than 12 tonnes per day. The average daily production in the EU is expected to be around 1 tonne per day[68]. Thus, a significant proportion of production falls outside the scope of this legislation.

Table 5.19 provides a summary of the advantages and drawbacks of the possible measures for the use of MCCPs in leather fat liquors.
The costs of substitution of MCCPs are relatively low (probably less than 0.002% of the turnover of the EU leather industry). Substitutes such as LCCPs or vegetable-based oils are expected to perform at least as well as MCCPs in terms of technical efficacy. In addition, the costs of introducing requirements to comply with any legislation through the Water Framework Directive or similar would be expected to be significantly higher than substitution of MCCPs.

Whilst the IPPC regime provides a mechanism for regulating emissions from tanneries using MCCPs, it only applies to a relatively small number of the largest tanneries. Most

[68] There are around 3,000 companies in the EU-15, producing around 325 million square metres of leather per year. Assuming an average density of 950 kg/m^3 and a thickness of 3mm, this equates to just over 900,000 tonnes of finished product per year. Assuming an average production of 300 days per year, this equates to 3,000 tonnes per day, or around 1 tonne per company.

of the smaller companies fall outside the scope of this legislation and hence introducing emissions controls could be relatively problematic.
In addition, given the large number of companies involved in the industry, it is considered impractical to introduce a voluntary agreement to either reduce emissions or to discontinue use of MCCPs. Indeed, the trade association representing the leather industry in Europe (Cotance) has indicated that it agrees with implementation of marketing and use restrictions for this sector. This is detailed further in Appendix B.

Table 5.19 Advantages and drawbacks of possible measures for use in leather fat liquors

Option	Advantages	Drawbacks
1) Limiting emissions through legislation	Could reduce the environmental risks associated with MCCPs without introducing possible risks associated with substitutes.	Costs could be significant - expected to be much larger than those for substitution of MCCPs - e.g. up to €130,000 - €500,000 annual cost of substitution in EU divided amongst e.g. 85 companies is around €1,500 to €6,000 per annum, significantly less than the cost of installing e.g. biological treatment. However, some larger companies already covered by IPPC Directive, for which substitution of chlorinated paraffins is already recommended as BAT.
2) Limiting emissions through voluntary agreement	Could potentially be introduced more quickly than legislation. Could reduce the environmental risks associated with MCCPs without introducing possible risks associated with substitutes.	Large number of companies (see below) and expected to be difficult to identify users of MCCPs (many sales through distributors). Also expected to be difficult to gain significant sign-up to voluntary agreement, given relative unimportance of MCCPs to the sector (confirmed by Cotance).
3) Restricting marketing and use through legislation	Would eliminate the risks associated with MCCPs. Risks for other uses expected to be lower (e.g. vegetable oils, LCCPs [1]).	Estimated annual costs for EU of using substitute are €130,000 to €500,000.
4) Restricting Uses Through a Voluntary Commitment	Could reduce the environmental risks associated with MCCPs without introducing possible risks associated with substitutes. Avoids the need for legislation, with reduced costs for the authorities.	Estimated annual costs for EU of using substitute are €130,000 to €500,000. Consultation with potentially large number of small users is problematic (e.g. 2400 leather companies in Italy - MCCPs estimated to be used in 3.5% of EU leather, perhaps 85 companies).

[1] Initial unpublished results of a UK risk assessment suggest PEC/PNEC ratios are generally significantly lower for LCCPs than MCCPs.

Based on the balance of advantages and drawbacks, it is considered that the most appropriate means for controlling the risks associated with MCCPs would be through introducing legislation to prohibit marketing and use in this application.

Carbonless copy paper

The latest information suggests that MCCPs are no longer used in this application. Therefore, the information presented in this section is included for information purposes only (based on previous versions of the risk reduction strategy).

Based on the latest version of the risk assessment, the only endpoint where there is a need for limiting the risks associated with recycling of carbonless copy paper is for the sediment compartment where the PEC/PNEC ratio is 1.1.

The use of MCCPs for this application has dropped significantly, from around 1,300 tonnes in 1997 to less than 100 tonnes in 2003.

Table 5.20 provides a summary of the advantages and drawbacks of the possible measures.

Table 5.20 Advantages and drawbacks of options for carbonless copy paper recycling

Option	Advantages	Drawbacks
1) Limiting emissions through legislation	Would reduce emissions of MCCPs to acceptable levels and also reduce emissions of other pollutants (if controls at paper recycling sites introduced).	Possible annualised costs of €137 million per year if water treatment controls introduced at all paper recycling plant (though costs may be lower depending on penetration of secondary treatment, as discussed in Appendix B).
2) Limiting emissions through voluntary agreement	Potentially greater flexibility in method and timeframe for implementation than (1).	Likely to be difficult to obtain sufficient coverage given large number of companies. Same costs as for (1) apply.
3) Restricting marketing and use through legislation	Would remove all risks associated with MCCPs. Companies mainly expected to be using alternatives already so costs for industry expected to be small.	Significant costs associated with introduction of legislation. However, costs of substitutes expected to be relatively similar.
4) Restricting Uses Through a Voluntary Commitment	Companies already essentially have an agreement not to use MCCPs (representing 95% of carbonless paper production).	Reduces availability of raw materials for companies to use with potential financial implications (e.g. when cost of alternatives rises above that of MCCPs).

Given that the highest PEC/PNEC ratio for this use is 1.1; that the use of MCCPs has declined to nil in recent years; that there would be significant costs associated with introducing emissions controls; and that there is already an industry agreement covering 95% of the EU industry to not use MCCPs, it is concluded that:

- Measures under the Water Framework Directive and the IPPC Directive, if adopted to target other uses, should be sufficient to address any remaining risks associated with this use.
- It may be appropriate to confirm compliance with (or even give formal recognition to) the industry (AEMCP) agreement not to use MCCPs.

A risk not directly addressed through these measures would be the legacy issue of recycling of carbonless paper containing MCCPs which is already in circulation. It is considered that there is no means of either segregating this paper or of requiring abatement equipment which would not pose disproportionate costs. However, since this use has been discontinued, this concern will be reduced and eventually eliminated over time.

Waste remaining in the environment

As indicated in the risk assessment, a need for limiting the risks to the terrestrial environment was identified in relation to 'waste remaining in the environment'. This relates to potential loss of MCCPs as part of products during their service life (e.g. due to erosion/particulate losses of particulate matter).

However, the risk assessment concludes that there are many uncertainties inherent in this scenario. In particular, the estimation of the PEC is based on tentative calculations and there are large inherent uncertainties, particularly over the actual (bio)availability of MCCPs and residence time in soil. Furthermore, no monitoring data were available that could be considered representative of this scenario. PEC/PNEC ratios were not provided.

Given these uncertainties, it is considered inappropriate to propose measures to address the identified risks based on the potential for limiting the risks using the PEC/PNEC ratios. However, consideration is given in Section 6 to possible action to address this possible risk which may be considered to be more significant if MCCPs are determined to have PBT properties.

Cross-cutting measures

In the preceding sections, a number of options have been identified as those that are likely to present the most appropriate balance of advantages and drawbacks for each sector where a need for limiting the risks is identified.

For some of these sectors, it was concluded that one means of ensuring a long-term reduction in emissions of MCCPs would be to introduce legislation on the control of emissions, particularly through the IPPC Directive regime where relevant and through the Water Framework Directive regime in relation to all sources of emissions.
It is considered that such general emissions reduction requirements could provide significant reductions in emissions by (a) ensuring that processes that are already regulated take appropriate steps to ensure/demonstrate that their emissions of MCCPs do not pose an unacceptable risk; and (b) ensuring that where MCCPs are used across all sectors, emissions are controlled to the degree possible (taking into account the large number of small companies in some sectors).

Such measures are also considered appropriate given that levels of MCCPs in the environment are considered to be significant[69] and there is an identified risk for a large number of different uses, for some of which, substitution of MCCPs is not likely to be practicable, either on technical or financial grounds.

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[69] For example, measured levels in the environment for surface water and sediment are of a comparable level to those predicted in the risk assessment, although there may have been reductions in concentrations, perhaps due to improved waste management practices. However, there remain concerns regarding the use of analytical methods for detection of MCCPs (Environment Agency, 2004).

As detailed in this report, a number of the potential substitutes for MCCPs in some of the key applications (such as metalworking and flame-retardant polymers including PVC), have concerns in relation to their environmental hazards. Requiring substitution of MCCPs in several of these applications, therefore, would not necessarily lead to a reduction in overall risks to the environment. Furthermore, a key conclusion of this risk reduction strategy is that it is likely that not all installations will cause a need for limiting the risks based on a PEC/PNEC approach. These factors should be taken into account in taking forward the risk reduction strategy for MCCPs, indicating that use-specific (rather than substance-specific) controls on environmental emissions are likely to be of greater net benefit in relation to controlling those risks.

A key aspect of achieving reductions in emissions and the necessary monitoring associated with this is the need for a robust and widely accepted method for monitoring concentrations of MCCPs in water and effluent samples. In order to ensure the success of these measures, it is considered appropriate to pursue development of an accredited analytical method (e.g. based on CEN standards).

Overall, it is concluded that the following cross-cutting measures (in combination with those identified for specific uses) would help to ensure that the environmental risks associated with MCCPs are adequately controlled:

- For the European Commission to consider including MCCPs as a priority substance under the Water Framework Directive when that list is next reviewed (see Sections 4 and 5);
- To work towards development and acceptance of an analytical method for accurately measuring MCCPs in water and effluent (see Section 5);
- For the authorities to take into account the conclusions of the risk assessment in developing/amending guidance under the IPPC regime and to take into account specific emission limit values for MCCPs where appropriate (e.g. for larger metalworking and plastics installations (see Section 4); and

In addition, the revised environmental classification and labelling requirements for MCCPs is also expected to contribute to ensuring appropriate controls on emissions and this will need to be communicated to users. However, there remains a need for more specific measures, as outlined in this report.

Dissemination of best practice by industry

The producers of MCCPs have expressed a willingness to continue to pursue the development and dissemination of best practice in use of MCCPs throughout the EU (expanding upon the work undertaken in the context of the UK Chemicals Stakeholder Forum).

In particular, Eurochlor, the association representing the EU producers of MCCPs, has indicated that the programme of best practice initiated in the UK[70] will be extended to

[70] Through the UK Chemicals Stakeholder Forum and the MCCP Best Practice User Forum, as discussed in Section 2.

the whole of Europe by MCCP manufacturers in order to control emissions. This will be undertaken under the auspices of Eurochlor. Under this programme, customers and trade associations were encouraged to sign a voluntary agreement to adopt and recommend best practice (CSF, 2004).

It is considered that this is a suitable means by which the conclusions of the risk assessment on a need for limiting the risks could be communicated to downstream users. By including in this programme sector-specific information on the potential risks associated with MCCPs, likely emissions routes and potential control measures, a significant contribution to raising awareness and reducing emissions of MCCPs across the EU could potentially be made. This could make a key contribution to successfully addressing the identified risks.

It is considered that this has the potential to achieve additional reductions in emissions if such best practice is taken up more widely. Therefore, it is recommended that the producers examine the potential for dissemination of best practice regarding reducing emissions of MCCPs, taking into account the potential for significant risks to the environment where emissions are not adequately controlled. It is envisaged that this would be done as a matter of course under REACH, where the application of risk reduction measures in order to achieve adequate control will have to be communicated in safety data sheets.

CONCLUSIONS AND RECOMMENDATIONS

Conclusions

Risk assessment

Section 2 of this report summarises the results of the environmental risk assessment of MCCPs. This assessment indicates that MCCPs are very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment.

The environmental risk assessment considered the full range of uses of MCCPs and developed predicted concentrations in various environmental compartments taking into account releases from these uses. A need for limiting the risks has been identified for the use of MCCPs in compounding and conversion of PVC, during formulation and use of metalworking fluids, in rubber/polymers other than PVC, in formulation and use of leather fat liquors and in recycling of carbonless paper (though the latter use is no longer expected to occur).

The risk assessment also identified a concern in relation to the possible PBT properties of MCCPs, though testing is still underway to determine whether MCCPs fulfil the criteria for categorisation as a PBT substance (the outcome is not expected until 2009). A need for limiting the risks was identified for various environmental compartments, including surface water, sediment and soil. In addition, due to the bioconcentration of MCCPs from water and biomagnification in food chains, a need for limiting the risks associated with secondary poisoning has also been identified (for the earthworm-based food chain).

The level of risk reduction required varies markedly amongst the different uses of MCCPs, as does the extent to which each of the uses contributes to overall environmental concentrations (at the continental level).

Whilst there is a need for limiting the risks associated with uses covering most of the sales of MCCPs, the risk assessment is based on a realistic worst case analysis. Therefore, whilst the worst-case sites are considered to lead to an unacceptable risk, other sites undertaking comparable uses of MCCPs will not necessarily make a significant contribution to environmental risks.

Existing risk reduction measures

A number of legislative and other measures that are expected to directly or indirectly affect the risks associated with MCCPs have been identified, as outlined in Section 3. These include national level measures taken in the EU Member States and other countries, as well as EU-level legislation such as marketing and use restrictions on SCCPs, the Integrated Pollution Prevention and Control Directive and the Water

Framework Directive. They also include controls on the disposal of waste oils and other chlorinated wastes.

Despite the existence of these measures, there remains a need for limiting the environmental risks associated with MCCPs at the EU-level, given that most of the sectors will generally not be comprehensively regulated in relation to emissions of MCCPs. However, it is recognised that – for most if not all of the sectors – there will be a potentially significant number of companies where emissions are already well controlled and environmental risks will be much lower than those of the worst-case sites covered by the risk assessment. This has been taken into account in undertaking the work on this risk reduction strategy.

Possible further measures

A number of potential measures for addressing the risks were considered. These possible measures are described in Section 4 of this report and include:

- Limiting/reducing emissions to the environment via legislation;
- Limiting/reducing emissions to the environment via a voluntary commitment;
- Restricting the marketing and use of MCCPs through legislation;
- Restricting certain uses of MCCPs through a voluntary commitment; and
- Implications of revised classification and labelling in relation to health and environmental effects.

Advantages and drawbacks of possible measures

Section 5 of this report provides a systematic consideration of the likely impacts of the possible measures in terms of their effectiveness, practicality, economic impact and monitorability. This is based mainly on qualitative information and builds upon the background information in Appendix B and elsewhere in this report.
Quantified information on the levels of reduction in risk and the compliance costs of the risk reduction options has been provided where it is practicable to do so. This has been based on information provided through consultation with stakeholders and estimates developed by Entec.

It is considered that the quantitative data, supplemented with qualitative information on the likely impacts of the possible measures for each sector, provides a suitable basis for understanding the likely consequences of implementing those measures and for determining the most appropriate strategy for each sector.

Section 5 includes a summary of the advantages and drawbacks of each of the measures considered for each of the sectors where a need for limiting the risks has been identified. Conclusions on what represents the most appropriate option or combination of options – based on the balance of advantages and drawbacks – have been provided for each sector, along with some cross-cutting measures that could apply to several uses of MCCPs where a need for limiting the risks has been identified.

Overview of approach to drawing conclusions

Conclusions on appropriate measures based on the risk assessment

As indicated above, each of the possible risk reduction options has been assessed taking into account the effectiveness, practicality, economic impact and monitorability of the options for each of the uses of MCCPs for which the need to reduce the risk was identified taking into account existing measures.

The risk reduction strategy has been developed based on the conclusions of the risk assessment (primarily the PEC/PNEC ratios) and the existing measures that are understood to be applied within each of the sectors.
The majority of the conclusions in the risk reduction strategy (draft of February 2008) were agreed at the 15th risk reduction strategy meeting.

However, at this meeting, several Member States indicated that they foresaw a need for further (precautionary) restrictions on marketing and use of MCCPs than was concluded to be appropriate in the risk reduction strategy based on the PEC/PNEC ratios approach. This was on the basis of current uncertainties regarding the PBT status of MCCPs. This has been taken into account in the following sections.

Consideration of restrictions on marketing and use

Where marketing and use restrictions have been considered, a range of factors have been taken into account, including:

- Firstly, whether the risks could be controlled through other measures that would impose less significant economic implications on EU industry;
- Whether there are available alternatives to use of MCCPs;
- Information available on the hazards and risks of those alternatives, including the associated uncertainties;
- The technical suitability of potential alternatives for the various uses of MCCPs;
- The economic implications of replacing MCCPs with alternatives.

Whilst the approach to determining whether restrictions are appropriate for any given use of MCCPs has been as objective and systematic as possible in practical terms, it is inevitable that there will be some degree of judgement involved in drawing overall conclusions.

This is particularly true with regard to the potential PBT properties of MCCPs and the recommendation in the risk assessment that consideration be given to possible precautionary action given the current uncertainties on this aspect. The analysis below takes into account the views of several Member States that further restrictions may be warranted on the basis of possible PBT properties (this is included in a separate section).

Measures to address quantifiable risks

Overview

Quantifiable risks in this context relates to risks identified in the risk assessment based on the PEC/PNEC ratios calculated for each environmental compartment and each use of MCCPs.

It is concluded that there is no single measure that could be introduced to limit the risks associated with MCCPs and which would at the same time not pose significant drawbacks in terms of cost, technical efficacy or potential risks from substitutes. Therefore, it is concluded that a combination of measures is required.

In particular, controls under the Water Framework Directive and IPPC Directive could target a number of different uses and releases to the environment. These are considered as over-arching or cross-cutting measures. Following implementation of such measures, a number of additional measures are identified that are concluded to be suitable to address the residual risks.

Cross-cutting measures

Water Framework Directive

In order to address emissions to the environment from the range of installations, it is considered appropriate for the European Commission to consider the inclusion of MCCPs in the priority list of Annex X to Directive 2000/60/EC during the next review of this Annex

It is concluded that this measure could address a significant proportion of the identified risks (excluding those where additional specific measures are suggested below). In addition to addressing the risks to surface water, sediment and secondary poisoning via the fish-based food chain, achieving compliance with an EQS under the Water Framework Directive could substantially target risks to the terrestrial compartment and secondary poisoning via the earthworm-based food chain provided that emissions are reduced at source (as set out in Section 5.4.1 of this report).

It is recognised that the success of this measure is dependent upon the enforcement within the Member States and also that it will take some time until controls will be required to be in place. However, given the relative scale of the PEC/PNEC ratios (except where additional measures are proposed below to control the highest concentrations), it is considered that this approach is proportionate to the level of risk identified.

Following the 15th risk reduction strategy meeting, based on the results of the risk reduction strategy, the following measures were included in a draft recommendation on MCCPs (European Commission, 2008):

- *To consider the inclusion of MCCPs in the priority list of Annex X to Directive 2000/60/EC during the next review of this Annex.*

- *It is recommended that for river basins where emissions of MCCPs may cause a risk, the relevant Member State(s) establish EQSs and the national pollution reduction measures to achieve those EQS in 2015 shall be included in the river basin management plans in line with the provisions of Directive 2000/60/EC .*
- *Local emissions to the environment of MCCPs should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.*

IPPC Directive

In order to ensure that emissions from the largest installations in key sectors (PVC, metalworking, rubber/other polymers), it is considered appropriate for the conclusions of the risk assessment and this risk reduction strategy to be taken into account in ensuring that emissions from these installations do not cause environmental concentrations in excess of the PNEC value.

Following the 15th risk reduction strategy meeting, based on the results of the risk reduction strategy, the following measures were included in a draft recommendation on MCCPs (European Commission, 2008):

- *Competent authorities in the Member States concerned should lay down, in the permits issued under Directive 2008/1/EC of the European Parliament and of the Council , conditions, emission limit values or equivalent parameters or technical measures regarding MCCPs in order for the installations concerned to operate according to the best available techniques (hereinafter "BAT") taking into account the technical characteristic[s] of the installations concerned, their geographical location and the local environmental conditions.*
- *To facilitate permitting and monitoring under Directive 2008/1/EC MCCPs should be included in the ongoing work to develop guidance on 'Best Available Techniques'.*

Leather fat liquors

It is concluded that restricting the marketing and use of MCCPs is the most appropriate option for use in leather fat liquors. This is on the basis that the other possible measures considered could not be relied upon to effectively reduce the risks in a practical manner and because the economic impact of this measure is expected to be less significant than for other sectors. There are also understood to be widely used substitutes that are likely to pose lower risks for the environment.

Other measures, such as control under the IPPC Directive or voluntary agreements, are not considered to be sufficiently reliable alone to address the identified risks.

Metalworking fluids

Emulsifiable metalworking fluids

The identified risk relates to intermitent releases of large quantities of MCCPs in emulsifiable metalworking fluids.

For use in emulsifiable metalworking fluids, it is concluded that the most appropriate option is to ensure that legislation is in place to prevent the intermittent release of large quantities of fluids containing MCCPs (e.g. though ensuring that such wastes are properly disposed of).

Whilst existing legislation (such as the Waste Oils Directive, 75/439/EEC) effectively includes a requirement that should prevent releases such as this, this practice cannot be ruled out; it has been acknowledged that the Directive has not been well implemented and that waste oil collection rates remain too low. The new Directive on Waste appears to provide a means by which Member States would be required to ensure that risks to the environment are addressed (see Section 3.8).

If this measure is successful in addressing the intermittent release scenario, there will no longer be a concern for use in emulsifiable metalworking fluids and so wider restrictions on use of MCCPs in this application are not considered to be the most appropriate risk reduction option on the basis of the PEC/PNEC ratios approach.

Oil-based metalworking fluids

For oil-based metalworking fluids, the most appropriate means of control is considered to be through the IPPC Directive (this will only cover certain larger installations) and the Water Framework Directive, as described above.

Given the available information on alternatives to MCCPs, it is concluded that restrictions on the marketing and use of MCCPs in this application is not the most appropriate option at the current time based on the PEC/PNEC ratios approach to assessment of the risks. This is because:

- Whilst use of alternative metalworking fluids or alternative production techniques has been shown to be possible in certain applications, evidence from a wide range of sources suggests that substitution in certain extreme pressure applications is not technically feasible while preserving the desired properties of the end product. It has not been possible to draw up a comprehensive list of applications where this is the case but those identified as potentially falling into this category include deep drawing; punching; extrusion; pilgering; forming; drilling; tapping; rimming; threading; boring; and broaching.
- Whilst there is a wide range of potential alternatives to MCCPs that may be used for certain applications, the available information suggests that these may have properties that could pose significant risks to health and/or the environment.

If any future decision is taken to restrict use of MCCPs, these considerations should be taken into account.

Use in PVC

Overall conclusion

For use of MCCPs in PVC, it is considered that the approach representing the most appropriate balance of advantages and drawbacks would be to ensure that emissions are controlled to an adequate level through inclusion of MCCPs as a priority substance under the Water Framework Directive (with subsequent measures to set and achieve an EQS) and control of emissions from those (larger) installations covered by the IPPC Directive in accordance with the conclusions of the risk assessment.

These measures could be expected to significantly reduce emissions of MCCPs below the levels identified in the risk assessment. The costs of implementing these measures for operators are estimated to be significantly less than for replacement under marketing and use restrictions. Moreover, this approach would not (directly) introduce additional risks associated with the use of substitutes, several of which are also have concerns in relation to environmental impacts.

However, this does not take into account the implications for environmental risks if MCCPs are determined to have PBT properties and this is considered in more detail in Section 6.4.

Uses where only a plasticising effect is required

In applications where MCCPs are used primarily for their plasticising properties, there are available alternatives that could be used which appear to pose lower risks for the environment (e.g. DINP). Such alternatives will generally be considerably more expensive than MCCPs.

However, the economic impact of substitution is not the only factor that needs to be taken into account in determining the most appropriate risk reduction strategy. Information collated for this risk reduction strategy suggests that it is possible to control releases of MCCPs to the environment to a level where it could reasonably be expected that there would no longer be a need for limiting the risks (i.e. PEC/PNEC ratio <1; given that the realistic worst case assessment suggests that PEC/PNEC ratios are relatively low compared to some uses); as practices vary amongst sites. It is concluded that, if measures are taken to ensure that this achieved through the Water Framework Directive, for example, these risks could be addressed in a more proportionate manner.

Uses where flame retardancy is required

In relation to control of the identified risks, the same conclusions as apply to uses where MCCPs are used primarily for their plasticising effects also apply to uses where they are used for their flame retardant properties.

However, with regard to the implications of possible replacement of MCCPs, the available information suggests that the drawbacks of a possible restriction would be more significant for these uses. In particular:

- The economic implications of substitution would be expected to be significantly greater, due to the types of substances that would be required in order to achieve the same degree of flame retardancy.
- Whilst the available information on alternatives to MCCPs is less complete than that for MCCPs themselves, the information that is available suggests that identified alternatives may not lead to a significant reduction in risks (e.g.

preliminary PEC/PNEC ratios aryl phosphates are in several cases much higher than for MCCPs).

Losses during the service life of products

Whilst the risk assessment does not identify a specific need for limiting the risks associated with losses of MCCPs from PVC products during their service life, such releases may potentially be significant. This issue is potentially important in the context of the possible PBT properties of MCCPs, as described below.

Rubber and polymers other than PVC

Given that the total emissions from this sector are low, the highest PEC/PNEC ratio identified is only 1.23 and the potentially high costs of substituting MCCPs, it is concluded that the most appropriate controls for this use are for appropriate emission limit values to be introduced (where this is not already the case) under the IPPC regime and for controls to be introduced on discharges, emissions and losses through recommendation that MCCPs be included on the priority list of substances under the Water Framework Directive (see above).

As with PVC, there is the potential for quite significant releases from these products during their service life. Whilst the risk assessment does not identify a specific need for limiting the risks associated with losses of MCCPs from rubber/other polymer products during their service life, such releases may potentially be significant. This issue is potentially important in the context of the possible PBT properties of MCCPs, as described below.

Carbonless copy paper

Given that the highest PEC/PNEC ratio for this use is 1.1 and that the latest information suggests that use no longer occurs in this application, it is concluded that no further measures would be required at the current time to address the risks associated with this use.

In the event that MCCPs begin to be used in this application in the future, measures under the Water Framework Directive and the IPPC Directive, if adopted to target other uses, should be sufficient to address any remaining risks associated with this use.
It may be appropriate to confirm compliance with (or even give formal recognition to) the industry agreement not to use MCCPs in order to avoid future use of MCCPs in this application.

Other uses

For the other uses of MCCPs, including production of MCCPs, no need for limiting the risks is identified in the latest version of the risk assessment. For ‘waste remaining in the environment’ it is concluded that there is insufficient certainty with regard to the risk assessment conclusions to draw firm conclusions on the most appropriate risk reduction measures.

Therefore, no additional measures are considered appropriate for these uses based on the risks identified using the PEC/PNEC approach.

Summary of conclusions on most appropriate measures

Table 6.1 provides a summary of the measures that it has been concluded represent the best balance of advantages and drawbacks for each of the relevant sectors in relation to the identified risks.

Table 6.1 Summary of conclusions on most appropriate measures

Use	M&U	IPPC	WFD	Waste oils
Metalworking		✓	✓	✓
Leather	✓			
PVC		✓	✓	
Rubber / other polymers			✓	
Carbonless copy paper [1]		✓	✓	
Other uses		✓	✓	

[1] It may also be appropriate to verify compliance with (or even give formal recognition to) the AEMCP industry agreement not to use MCCPs. Note that use no longer occurs in this application.

Possible further restrictions

The above discussion relates to measures that are concluded to be appropriate to address the environmental risks associated with MCCPs based on the uses for which a need for limiting the risks has been identified using the PEC/PNEC ratios approach. It is considered that the measures identified above represent the best balance of advantages and drawbacks for society as a whole, taking into account the level of risk identified based on those PEC/PNEC ratios.

However, the updated version of the risk assessment also concludes that consideration may need to be given to precautionary action to address the possible PBT properties of MCCPs, including the implications of ‘waste remaining in the environment’. In particular, it was not possible to say on a scientific basis whether there is a current or future risk to the environment related to the possible PBT properties of MCCPs.
The need for possible precautionary action was identified because of: data indicating presence in marine biota; the apparent persistence of the substance; the time it would take to gather information to confirm whether MCCPs fulfil the PBT criteria; and the fact that it could be difficult to reduce exposure if the additional information confirmed a risk.

The majority of the risk reduction strategy was agreed at the 15th risk reduction strategy meeting (as incorporated into the draft recommendation on MCCPs to be handed over to ECHA, ES/12f/2007 Rev. 1).

However, the extent of the proposed restrictions on use (limited to use in leather fat liquors, as described above) was questioned with several Member States indicating a need for precautionary action to be taken given the current uncertainties regarding the PBT status of MCCPs and suggesting that further restrictions would be appropriate, particularly for metalworking fluids and PVC[71].

This document is intended to reflect the outcome of an objective and impartial analysis of available options to address the risks associated with MCCPs. It is not considered appropriate to provide advice for or against any possible precautionary action to restrict the use of MCCPs within this document as any decision to take precautionary action should be based on a political judgement[72]. Appendix E provides information from the February 2008 draft of this risk reduction strategy (presented at the 15th risk reduction strategy meeting) regarding factors that may be taken into account in any such precautionary decision.

The assertion by several Member States that restrictions on other uses would be warranted on a precautionary basis should be taken into account at a political level in determining what restrictions, if any, are taken forward for MCCPs.

Work on determining the potential PBT properties of MCCPs is still underway and is not expected to be complete before 2009.

If MCCPs are determined to have PBT properties, it may be concluded that MCCPs would be a suitable candidate for inclusion on Annex XIV under REACH (i.e. substances subject to Authorisation). According to Article 58(3) of the REACH Regulation, in making any decision to include substances on Annex XIV, priority shall normally be given to substances with:

(a) PBT or vPvB properties; or
(b) wide dispersive use; or
(c) high volumes.

If MCCPs are determined to have PBT properties, they could be concluded to fulfil all of these criteria. They may be concluded to have a wide dispersive use, particularly given that MCCPs are used at many sites (e.g. metalworking uses) and that the risk assessment concludes that releases during service life may be significant. They are also used in high volumes, nearly 64,000 tonnes in the EU in 2006.

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71 Draft summary record of the 15th Risk reduction strategy meeting of the Member States for the implementation of Council Regulation (EEC) 793/93 on the evaluation and control of risks of existing substances, 22-24 April 2008, (Doc. ES/05/2008).

72 See for example, Communication from the Commission on the precautionary principle, COM(2000)1 final, Brussels, 2.2.2000.

Taking into account the outcome of the ongoing testing on possible PBT properties of MCCPs, ECHA may wish to consider whether it would be appropriate to include MCCPs on Annex XIV of the REACH Regulation.

Recommendations

The information available for preparation of this report is considered to provide a suitable basis for determining which measures are likely to be most appropriate for each sector (although the level of information available differs significantly amongst the sectors) based on the risks identified using PEC/PNEC ratios. The measures identified are considered sufficient to address the risks identified on that basis though they will not necessarily address the risks identified on the basis of the *possible* PBT properties of MCCPs.

The elements of this risk reduction strategy that do not relate to restrictions were agreed at the 15^{th} risk reduction strategy meeting. Furthermore, it was concluded that restrictions on the marketing and use of MCCPs in leather were the most appropriate risk reduction option for this use. It is recommended that the UK Government takes the findings of this report into account in the Annex XV dossier being prepared for MCCPs under REACH.

With regard to any possible further controls on MCCPs, it is recommended that the findings of this report, along with the results of the ongoing testing to determine PBT properties and the views of Member States expressed at the 15^{th} risk reduction strategy meeting, be taken into account in determining the most appropriate means of addressing the risks.

It is also recommended that consideration be given by industry to the acceptability and practicability of the identified measures where the most appropriate option involves possible negotiated/voluntary action to reduce the risks.

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Appendix A
List of Organisations Contacted

A list of the main organisations that have been contacted for the purposes of this project is included below. This includes a number of organisations from which detailed information is still to be received.

Note that all of the EU Member States competent authorities for the Existing Substances Regulation have been contacted. Only those that provided information in relation to MCCPs are included in this appendix.

Association of European Manufacturers of Carbonless Paper
Akzo Nobel Coatings (Hungary)
AlphaGary
Altro
Arjo Wiggins
Australia - National Industrial Chemicals Notification and Assessment Scheme
BLIC - European Association of the Rubber Industry
Boss Paints
British Lubricants Federation
British Rubber Manufacturers Association
Caffaro
Carrs Paper
CEFIC - European Chemical Industry Council
CEPE - European Council of the Paint, Printing Ink and Artists' Colours Industry
Chance & Hunt
Chlorinated Paraffins Industry Association
Confederation of Paper Industries
COTANCE - of National Associations of Tanners and Dressers of the European Community
Cyprus - Department of Labour Inspection
Denmark - Environmental Protection Agency
Danish Paintmakers Association
Department of Health
Doeflex Vitapol
Dover Chemicals
Environment Agency for England and Wales
Environment Canada
European Resilient Flooring Manufacturers Institute
European Chemicals Bureau (OMNIITOX Project)
European Recovered Paper Council
European Vinyls Corporation
Finland - Finnish Environment Institute
France competent authority - INRS and INERIS

Germany - Institute for Occupational Safety and Health
Germany - Federal Environmental Agency
Graham & Brown
Health & Safety Executive (UK)
Hydro Polymers
International Institute of Synthetic Rubber Producers
Independent Waste Paper Processors Association
Ineos Chlor
Japan - Ministry of Environment
Leuna Tenside
LGC Limited
Marley Floors
NCP Exports - Sentrachem
Netherlands - RIVM
Norway - Pollution Control Authority
Novácke chemické závody
Paper Chemicals Association
PITA
Polyflor
PVC Group
Quimica del Cinca
Sandvik Materials Technology
SCL Group
Shipley Paint
SigmaKalon
Slovakia - Centre for Chemical Substances and Preparations
Small Business Service (UK)
Sweden - National Chemicals Inspectorate
UEIL - Independent Union of the European Lubricant Industry
UNIC - Italian Leather Association
United States Environmental Protection Agency
VVVF (Netherlands)

Appendix B
Sectoral Analysis

Contents of Appendix B

B1 Production of MCCPs

B1.1 Consultation Undertaken

Information has been provided by all of the European producers of MCCPs for this risk reduction strategy. There are currently thought to be six sites involved in production of MCCPs in the enlarged EU. Based on the information provided, it is estimated that just over 60% of the EU production of MCCPs is sold in the EU (around 54kt, as outlined in Section 1), with the remaining exported to outside the EU (around 36kt).
Information was sought and provided on the nature and sizes of the companies concerned; current controls on MCCP emissions and potential for further reduction; the availability of substitutes for MCCPs; and views on the potential risk reduction measures being considered.

Of the five companies that provided information, two have between 50 and 250 employees, with the remaining three having more than 250 employees. One company has an annual turnover less than €10 million; one has a turnover in the range €10 to €50 million and the remaining three have a turnover greater than €50 million. Thus, according to the European Commission's criteria, one of the companies concerned would be considered a small company on the basis of turnover (but not number of employees). Two companies would be considered medium-sized on the basis of both employees and turnover.

B1.2 Current Controls and Potential for Further Reduction

Table B1.1 provides a summary of information from MCCP producers on current controls in emissions and the extent to which further controls could be introduced.

Table B1.1 Emissions Controls at MCCP Producers

Site [1]	Current Controls	Potential for Further Controls
M1	Paraffin chlorination is a closed operation where process waste-water and air emissions are not generated. MCCPs may be released to the environment via spills and/or floor wash-water. This wash-water is directed to a settling tank. Amounts of MCCPs entrained by settled wash-water are very small.	No information provided.
M2	Estimation sent in 1998 for risk assessment was maximum concentration in effluents. MCCPs plant is similar to a closed system. So actual emissions will be less than risk assessment assumed. Small leakages in loading trucks or in drumming operations are absorbed on inert materials and sent to incineration plants.	Additional organic absorption steps.

Site [1]	Current Controls	Potential for Further Controls
M3	Organics separated from CPs plant by three-stage filtration process, including a third stage of carbon absorption. Treated effluent (with 2-3 ppm total organics) then sent to Environmental Improvement Plant including physico-chemical flocculation (provides considerable surface area for adsorption of MCCPs), followed by activated carbon absorption.	Already spent £50m (€80m) on EIP for the site and achieved a 90% reduction on total organo-chlorine emissions. Additional carbon filter bed on the aqueous stream from the chlorinated paraffin plant would cost around £100 k, but the ability to reduce the levels significantly would be limited.
M4	Occasional washings settled and supernatant liquid measured for AOX to assess compliance with outfall limit. All effluents undergo biological treatment.	Carbon filter bed on aqueous stream from settling vessel would cost around £50k.
M5	No information provided.	-
M6	Sewage traps, off-gases cleaning by cooling and demister.	Double walled storage tanks, drum filling exhaust disposal at cost of €500k (no operational costs).

[1] Not in the same order as listed in the environmental risk assessment. Includes one site not covered in the risk assessment due to enlargement of the EU.

Producers generally expressed a willingness to undertake monitoring of effluents to ensure that concentrations are below specified levels, although the availability of a reliable analytical methodology is questionable. The cost of such monitoring could be significant with one company indicating possible costs for weekly monitoring of £10,000 per annum.

Based on the information in Table B1.1, it appears that there are steps that could be taken to reduce emissions of MCCPs to within acceptable levels: the highest PEC/PNEC ratio for production is only 3.4 and companies have provided data on potential abatement methods such as carbon absorption. In one case, such abatement has already been implemented and it would be expected that the 90% reduction in total chlorinated organics would lead to a proportionate reduction in emissions of MCCPs, hence reducing all PEC/PNEC ratios to below unity.

B1.3 Potential Substitutes for MCCPs

Companies generally indicated that end-users are best placed to advise on potential substitutes for MCCPs. One company indicated that long chain chlorinated paraffins are suitable substitutes for paints, with esters are suitable for metalworking. Companies also expressed a desire that any substitute for MCCPs should be assessed as fully as MCCPs in terms of its environmental and health hazards and risks.

B1.4 Industry Views on Implementing a Risk Reduction Strategy

Table B1.2 summarises the producers' views on the most appropriate method for implementation of a risk reduction strategy.

Table B1.2 MCCP Producers' Views on Most Appropriate Risk Reduction Strategy

Site [1]	Negotiated Agreement on Emissions	Legislation on Emissions	Legal Restrictions on Marketing and Use	Voluntary Cessation of Certain Uses
M1	Preferred option	Could accept	No	No
M2	Preferred option	Could accept	No	No
M3	Preferred option	Could accept	No	No
M4	Preferred option	Could accept	No	No
M5	-	-	-	-
M6	Yes	-	-	-

No information on this issue was provided by site 5. The producers of MCCPs provided a co-ordinated response on this issue.

It is evident from the above that the preferred option for producers of MCCPs would be to introduce limits on emissions based on a negotiated agreement. An alternative option that would be acceptable to producers would be to introduce legislation to restrict emissions.

However, the producers have indicated that a suitable analytical methodology would have to be developed in order for effective monitoring of any reduction in emissions to be effective.

There would obviously be significant economic implications associated with any reduction in uses of MCCPs through legislation or otherwise: the total sales, including extra-EU exports, are estimated to be worth around €45 million per year (compared to around €28 million for sales in the EU).

In addition, one of the producers has indicated that they believe action should be taken to reduce the impacts of the worst cases in relation to environmental risks while allowing responsible use to continue. This comment relates to the fact that the risk assessment is derived based upon a realistic worst case assessment.

B2 Use in PVC

B2.1 Consultation Undertaken

Input to the project has been provided by several companies using MCCPs in production of PVC wallcoverings, flooring and compounds for PVC cables. These companies represent over 3,000 tonnes annual use of MCCPs, over 10% of total usage.

B2.2 Current Controls and Potential for Further Reduction

From the consultation undertaken on the existing controls in place, it is evident that there exists a range of techniques already in place for control of emissions of MCCPs (along with other pollutants). Examples of these are summarised in Table B2.1.

Table B2.1 Examples of Techniques in Place for Control of Emissions (PVC)

Company	Application	Control Techniques
PVC1	Wallcoverings	▪ Thermal oxidiser
PVC2	Wallcoverings	▪ Bunded tank farms. ▪ No access to water courses in mixing and usage areas. ▪ All fumes passed through incinerators.
PVC3	Floor covering	▪ Electrostatic and candle filters
PVC4	Safety Floorings	▪ No drains within the mixing area ▪ Fume abatement equipment on all ovens and other extraction equipment where the product is heated. ▪ Emissions are monitored on an annual basis
PVC5	Calendering and spread coating (flooring)	▪ Fume arrestment plant

The only means by which consultees identified the potential for further reductions was through e.g. modifying fume abatement equipment to improve efficiency by extra cooling (site PVC4); and introduction of incineration and carbon filters (site PVC5).

Based on the assumptions in the risk assessment, the main means by which emissions of MCCPs to the aquatic environment may occur is through either spillage during raw materials handling and also through initial losses to air which subsequently and are washed to waste water (e.g. during equipment cleaning). From the techniques in place in the companies providing information for the risk reduction strategy, it appears that companies will often have equipment/procedures in place that should ensure emissions are controlled to an acceptable level. In particular, these include:

- Ensuring that there are no surface water/sewer drains within key areas such as in raw materials handling, mixing and in areas with ovens in place (where initial emissions to air are likely to be greatest); and
- Use of thermal oxidation/incineration or use of filters to control emissions of MCCPs and other pollutants.

Of the companies that provided information, three out of five did not identify any further abatement techniques that could be used to reduce the identified emissions sources further. Indeed, it is expected that the emissions at these sites will be already controlled to an acceptable level (since the key pathways to the environment are targeted). However, one company with fume abatement equipment in place already indicated that the efficiency of such equipment could be improved further by providing extra cooling[73]. Another company indicated that incineration of emissions combined with carbon filters could be introduced at a cost of expected to exceed €150,000 in capital expenditure.
If further controls on emissions were required in order to meet standards imposed through voluntary agreement or legislation, companies - if taking the least-cost option -

[73] The capital expenditure for this would be around €45,000 for introduction of a new cooler and associated changes to ductwork. There would not be an additional operation costs.

would determine whether to install additional abatement equipment or to substitute MCCPs based on their relative costs. However, those that have sufficient controls in place already would likely be required to demonstrate this through monitoring of emissions.

Whilst it is not practicable to determine how many companies would install abatement equipment and how many would substitute MCCPs, it is possible to estimate the costs of installing thermal oxidation equipment and for ensuring that emissions are not washed to wastewater.

For example, for introduction of thermal oxidation at PVC compounding/processing sites, assuming an average capital cost of €150,000 and an annual operating cost of €15,000, the annualised costs for one site would be around €33,000[74]. Based on the number of companies providing information for this project, the average consumption of MCCPs is around 650 tonnes per year and based on this average there would be expected to be around 50 sites using MCCPs, based on the current consumption of around 30,000 tonnes per year. For the purposes of this assessment, it is assumed that there are 100 companies, since larger companies are more likely to respond to exercises such as this. If it is assumed that 25-75% of these sites would need to install and operate thermal oxidation, the total costs for the EU could be around €0.8 to €2.5 million per year.

B2.3 Potential Substitutes for MCCPs

Information has been provided by the European Flame Retardants Association (EFRA, 2004) on the use of phosphate esters as possible replacements for MCCPs in PVC products. As confirmed elsewhere in this report, MCCPs only have relatively limited compatibility with PVC and so are used in conjunction with a primary plasticiser (phthalates or liquid triaryl or alkyldiaryl phosphate), mainly because their cost is lower than other plasticisers. Incorporation of a phosphate ester to replace MCCPs where fire performance is an issue would require modification of the formulation but actually improve processing and compatibility of the composition (i.e. exudation of the MCCP from the product is less likely). There would, however, be costs associated with reformulation and with the increased price of the alternatives. Alternatives available for use in PVC flooring, cables and coated fabrics include:

- cresyl diphenyl phosphate (CDP);
- tricresyl phosphate (TCP);
- trixylyl phosphate (TXP);
- isopropylated triphenyl phosphate (IPP);
- 2-ethylhexyl diphenyl phosphate (ODP - octyl diphenyl phosphate); and

74 Based on Entec (2003). Assuming recuperative thermal oxidation and a gas flow rate of 4000 Nm^3/h. Capital costs vary between £5,800 - 50,000 per 1000 Nm^3/h and annual operating costs between £1,500 - 3,800 per 1000 Nm^3/h. Values of £25,000 (€37.5,000) and £2,500 (€3,7500 per 1000 Nm^3/h respectively have been assumed. An operating life of 10 years and a discount rate of 3.5% have been assumed.

- isodecyl diphenyl phosphate (IDDP).

The key reason for use of MCCPs in wallcoverings appears to be due to the relative price as compared to primary plasticisers. Both companies that provided information for this work indicated that an alternative to the use of MCCPs would be to use only the primary plasticiser: usually di-isononyl phthalate (DINP).

For use in production of PVC flooring, cost is also a key factor but the flame retardancy imparted by MCCPs is also a key issue and some of the alternatives could have inferior performance in use or could cause discolouring to the finished product. Alternatives that have been suggested for PVC flooring include tri-alkyl phosphates or other phosphates, often in combination with solid flame retardants, such as borates.
For wallcoverings, the price of DINP is expected to be around €800 to €900 per tonne, as compared to around €500 per tonne for MCCPs. It is expected that the use of DINP would add 3-4% to the total raw material costs of the plastisol. It is understood that retailers will often be unwilling to accept this increase in costs being passed on from the manufacturers. DINP is considered by wallcovering manufacturers to have equivalent or even superior properties as compared to MCCPs and the relevant flammability tests can be passed without their use (i.e. there is sufficient flame retardancy within the PVC formulation, regardless of whether MCCPs or additional DINP is used).
For PVC flooring, the additional costs for use of tri-alkyl phosphates and a small amount of solid flame retardants could be expected to be around €1,900 per tonne of MCCPs[75].

For PVC cable manufacture, imparting additional flame retardancy to the PVC is not generally the main reason for use of MCCPs in most markets (MCCPs are used as a relatively inexpensive secondary plasticiser). In such cases, substitution with phthalates or trimellitates could be undertaken. However, in some markets, flame retardancy is an issue and flame retardants such as antimony trioxide or aluminium trihydrate could be used. For the purposes of this analysis, it is assumed that the *average* substitution cost would be around €800 per tonne, assuming that around two thirds of MCCP use could be substituted with phthalates at an *additional* cost of around €300 per tonne and that the remaining third would need to find alternative flame retardants, at a similar cost to substitution in PVC flooring (additional cost of €1,900 per tonne)[76].
For other uses in PVC, it is assumed that substitution with phthalates could be undertaken.

Table B2.2 summarises the total estimated annual costs associated with substituting MCCPs in each of the PVC applications, based on the assumptions detailed above.

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[75] Based on estimates from two companies. One company estimated annual substitution costs of around €2,140 per tonne. A second company estimated costs of around €1,500 per tonne for substitution with tri-alkyl phosphates plus additional costs of reformulation (around €45,000 per 100 tonnes which it is assumed will be borne over a period of three years). In addition, there would be a cost for the second company of using a small amount of solid flame retardant (e.g. borates) that would be required in combination with the tri-alkyl phosphates.
[76] One third times €1,900 plus two thirds times €300 equals approximately €800.

Consideration is given in Section 5 to the one-off costs of undertaking any reformulation required for substituting MCCPs.

Table B2.2 Estimated Costs of Substituting MCCPs in PVC Applications

Use	% of Total	Quantity	Substitutes	Additional Cost of Substitute (€/t)	Total Cost (€m per year)
Wallcoverings	33%	10,817	Phthalates	300	3.2
Flooring	33%	10,817	Tri-alkyl phosphates	1900	20.6
Cables	17%	5,408	Phthalates/tri-alkyl phosphates	800	4.3
Other	17%	5,408	Phthalates	300	1.6
Total	**100%**	**32,450**			**29.7**

B2.4 Industry Views on Implementing a Risk Reduction Strategy

Table B2.1 summarises the producers' views on the most appropriate method for implementation of a risk reduction strategy.

Table B2.1 PVC Wallcovering Manufacturers Views on Most Appropriate Risk Reduction Strategy

Site	Negotiated Agreement on Emissions	Legislation on Emissions	Legal Restrictions on Marketing and Use	Voluntary Cessation of Certain Uses
PVC1	Yes			
PVC2			Yes [1]	
PVC3	Yes			
PVC4	Yes			
PVC5	Yes			
PVC6	(Substituting MCCPs so no information provided)			

[1] The company indicated this as a preferred option because some large retail groups are reportedly pressing for a phased withdrawal of MCCPs but will not accept the associated increase in costs of products.

B3 Use in Metalworking Fluids

B3.1 Consultation Undertaken

For the purposes of Stages 2 and 3 of the risk reduction strategy, a questionnaire was disseminated by the Independent Union of the European Lubricant Industry (UEIL) to producers of metalworking fluids. However, no information has been forthcoming directly from these companies and the UEIL has commented that historically, responses to this type of request in this industry have been poor.

In addition to this, discussions have taken place with producers of MCCPs as well as UEIL representatives as regards the status of current controls on releases of MCCPs in the formulation and use of metalworking fluids. As detailed in Section 2, the risks associated with formulation of metalworking fluids are now expected to be significantly better controlled due to the widespread use of primary effluent treatment at EU sites. Furthermore, one company has provided specific information in relation to attempts to substitute MCCPs in certain metalworking applications and has provided a response to the questionnaire directly.

In general, the it is expected that emissions to the environment at many of the larger engineering companies undertaking metalworking operations will be well controlled. However, this is not necessarily true of smaller companies that make up by far the greatest proportion of the sector in terms of numbers of companies (though probably not in terms of quantities of MCCPs used).

B3.2 Current Controls and Potential for Further Reduction

Representatives of producers of MCCPs have suggested that legislation has been introduced since production of the emissions estimates used in the risk assessment and, they indicate, many of these practices are now prohibited. In particular, this relates to intermittent discharge of emulsifiable metalworking fluids to drain. However this may not be the case given that (based on the discussion in Section 3.7 of the main report) it is evident that such disposal does still occur in practice, where companies are issued with appropriate permits/consents to undertake such discharges. This is discussed in the main part of this report. However, as noted in Section 2 of the main report, most sites are expected to separate the oil phase from these fluids, with a resulting significant reduction in the level of risk.

Legislation has been in place for some time to control disposal of waste oils and their impacts on the environment. In particular, Council Directive 75/439/EEC[77] on the disposal of waste oil prohibits the following discharge of waste oils into drainage systems. Member States are required to ensure that waste oils are collected and disposed of (by processing, destruction, storage or tipping above or under ground) and must give priority to the processing of waste oils by regeneration (re-refining). However, in practice, the controls under this Directive may not be interpreted as extending to cover emulsifiable metalworking fluids containing MCCPs, perhaps because MCCPs may not be recognised as ‘oils’.

One large company, with sites in five EU Member States and using around 40-70 tonnes of MCCPs (in around 135 tonnes of chlorinated oils) per year has indicated that:

[77] OJ L 194, 25/07/1975, 23-25.

- All waste containing MCCPs is sent for external destruction by licensed companies;
- Rinsing water following degreasing is fed to an on-site sewage treatment plant. The possibility of separating chlorinated paraffins into a closed rinsing water system is being investigated; and
- The company has been working on continuous oil recirculation methods and on minimising leakages and spillages of chlorinated paraffins.

Thus, in general, disposal of neat oils containing MCCPs are expected to be well controlled under existing legislation. However, as discussed in Section 3, under the European Waste Catalogue, emulsions and solutions containing MCCPs may be excluded from certain aspects of the European waste legislation. Indeed, information from regulators in the UK (the Environment Agency for England and Wales) indicates that disposal of water-based metalworking fluids to drain is not necessarily prohibited, provided that a permit (discharge consent) is granted by the appropriate water company.

B3.3 Potential Substitutes for MCCPs

Consideration was given in Section 5 of this report to potential substitutes in metalworking fluids in a general context.

In relation to specific information provided for this study, the one company that has provided information thus far has undertaken research over more than 10 years to find alternatives to chlorinated paraffins at a cost of more than €3.5 million. Thus far, no suitable substitute has been identified. This company uses MCCPs in pilgering[78] where there is a significant reduction in area, resulting in high loads on tools and the worked steel. The tubular products are used in various applications, including the chemical industry, power generation, oil & gas industry and in the petrochemical industry. The company has not identified any suitable alternatives to chlorinated paraffins that provide the same degree of resistance to high temperature and pressure during this process and during deep drawing. The other potential extreme pressure additives considered include phosphorus and sulphur compounds, as discussed in Section 5.

For many years, sulphurised hydrocarbons and esters have been available as substitutes but these are considered to be more expensive and can reportedly cause corrosion problems. Acid alkyl phosphates and dialkyl phosphites (hydrogen phosphonates) also have good extreme pressure performance but are more difficult to formulate due to their high acidity or are economically less viable (EFRA, 2004). In addition, a recent improvement in technology is that neutral alkyl phosphates can work synergistically with sulphurised additives to achieve a performance level comparable to that of chlorinated paraffins and in a cost-effective manner.

[78] A process for making seamless steel tubes using a cold rolling process with simultaneous reduction in thickness and diameter.

B3.4 Industry Views on Implementing a Risk Reduction Strategy

The company discussed in Section B3.3, above, has indicated that legislation to reduce emissions of MCCPs to the environment would be the preferred risk reduction option, although they indicate that standardisation of monitoring techniques would need to be undertaken.

Consultation also indicates that - in the UK at least - many companies have been seeking alternatives to chlorinated paraffins for some time and that substitution with various substances such as sulphur and phosphorus based compounds. There is thus a general trend away from the use of MCCPs in metalworking. For example, there was a 25% reduction in sales to this application between 2002 and 2003 in the UK.

B4 Use in Paints

B4.1 Consultation Undertaken

Questionnaires were disseminated on behalf of Entec by CEPE to national coatings associations and then to individual companies. Thus far, eight companies have provided a response, of which six companies use MCCPs. The total quantity of MCCPs used by these companies is around 400 tonnes, as compared to the 1,180 tonnes of MCCPs assumed to be used in paints in the risk assessment report. The uses covered by these companies include:

- Anti-corrosive primers/topcoats;
- Outdoor wall paints;
- Chlorinated rubber paint;
- Protective coatings for metal;
- Antifouling paints; and
- Acrylic and epoxy underwater primers.

The countries covered by the responses include The Netherlands, Hungary, Denmark and the UK.

B4.2 Current Controls and Potential for Further Reduction

In relation to current controls in place for emissions from paint formulation, all of the companies providing information considered that there was little or no potential for emissions of MCCPs to occur to wastewater given that the processes involved were either closed or had no means of losses passing to wastewater (e.g. no drains present on the site). Since MCCPs are generally used in solvent-borne paints, it is expected that companies will clean equipment with organic solvents, rather than with water which can be washed to wastewater. For example, one company undertakes all equipment cleaning using xylene, which is then reused or recovered for use as a fuel.

Therefore, it is considered unlikely that any of the companies providing information for this study represent the realistic worst case assumed in the risk assessment report (which was based on the default emissions estimates from the risk assessment technical guidance document).

None of the companies that provided information identified any potential for further emissions abatement, although three out of the six indicated that they would be willing to undertake monitoring of emissions if required and if at reasonable cost.
If required, further abatement could potentially be achieved through use of techniques such as carbon adsorption of MCCPs in wastewater.

B4.3 Potential Substitutes for MCCPs

All of the potential substitutes for MCCPs in paints identified by consultees are included in Section 5.2 of the main report. No further discussion is provided here.

B4.4 Industry Views on Implementing a Risk Reduction Strategy

Table B4.1 summarises the producers' views on the most appropriate method for implementation of a risk reduction strategy.

Table B4.1 Paint Companies' Views on Most Appropriate Risk Reduction Strategy

Site	Negotiated Agreement on Emissions	Legislation on Emissions	Legal Restrictions on Marketing and Use	Voluntary Cessation of Certain Uses
PAINT1				Yes
PAINT2		Yes		Yes
PAINT3		Yes		
PAINT4	Yes	Yes		
PAINT5	Yes			
PAINT6				
PAINT7	Yes			
PAINT8				
PAINT9				

B5 Use in Rubber and Plastics other than PVC

B5.1 Consultation Undertaken

A questionnaire developed by Entec has been disseminated by the European Association of the Rubber Industry (BLIC). A number of companies provided a response to this questionnaire but these responses were collated by BLIC into a single response for the sector as a whole. These companies, based in Germany, represent approximately 40% of the EU market share in terms of production of these materials and it is considered that they are likely to be representative of the types of issues and associated costs and technical requirements. This is because the companies are usually large companies due to the typical nature of the product (e.g. large conveyor belts). Production using MCCPs is understood to take place on an intermittent basis, with other formulations being used at different times.

Companies with a total usage of 200 t/yr of MCCPs provided information. MCCPs are used by these companies in the following applications:

- Conveyor belts and tubes for compressed air in the mining industry;
- Bellows for buses, metros and trains; and
- Profiles for fireproof doors.

B5.2 Current Controls and Potential for Further Reduction

It is indicated by the industry that no measures to limit emissions of MCCPs are currently applied because the exposure is considered by them to be low. They indicate that emissions to air are considered low for all uses. In relation to emissions to wastewater, they indicate that emissions are not relevant for compounding, conveyor belts and bellows since there is no contact with water. For tubes for compressed air, emissions to wastewater are considered possible, depending upon the production method. For profiles, emissions through contact with cooling water were considered possible.

Techniques identified for further control of emissions include:

- Control of cooling water circuits (relevant for profiles);
- Filtering of air emissions; and
- Additional treatment of wastewater where parts that come into contact with MCCPs are cleaned.

However, no information on the level of investment required for these measures was provided.

B5.3 Potential Substitutes for MCCPs

Potential substitutes for MCCPs in rubbers and polymers other than PVC identified by consultees are included in Section 5.2 of the main report. No further discussion is provided here.

B5.4 Industry Views on Implementing a Risk Reduction Strategy

In relation to the various risk reduction measures being considered in the risk reduction strategy, the following comments were provided:

- Legislation to reduce emissions would be the preferred option since this would allow companies to decide upon their response (e.g. install abatement equipment or substitute MCCPs);
- The consultees believe that legal restrictions on MCCPs would lead to the closure of EU production facilities and associated jobs (due to competition from Asian manufacturers); and

- Voluntary cessation of certain uses would also not be preferred.

B6 Use in Leather Fat Liquors

B6.1 Consultation Undertaken

For the purposes of Stages 2 and 3 of the risk reduction strategy, a questionnaire was disseminated by COTANCE to its members. COTANCE consulted its member organisations, of which the British and Italian trade associations responded (Italy has the largest leather industry in the EU, accounting for over 80% of companies and over 65% of sales by volume and cost). The British Leather Confederation could not identify any company in the UK that could confirm that MCCPs are used in fatliquors, and the consensus is that they have been phased out. This is consistent with previous work on this issue (e.g. RPA, 2002 and work through the UK Chemicals Stakeholder Forum).

In response to COTANCE's request, the Italian tanning industry union, Unione Nazionale Industria Conciaria (UNIC), has consulted with suppliers of MCCPs to the metalworking industry and with fatliquors producers. Information from one producer indicates that SCCPs and MCCPs are not commonly used in the tanning sector, as compared to other fatliquoring agents. The most commonly used paraffins are those with a carbon chain length over C_{17} - i.e. LCCPs. The Unione also stated that, in general, MCCPs did not perform as well in producing the required qualities (softness, light solidity, etc).

It appears that almost all of the MCCPs that are used in leather fat liquors are used in Italy (a figure of around 1,000 tonnes per year has been quoted, as compared to around 1,300 tonnes sold into this application in 2003 for the EU as a whole, of which only around 30% are used in the EU).

In addition, the leather industry associations have been consulted on the views on the most appropriate risk reduction strategy for this sector (see Section B6.4, below).

B6.2 Current Controls and Potential for Further Reduction

Whilst no information is available on a EU-wide scale, action has been taken in the UK by the British Leather Confederation in relation to MCCPs (BLC, 2003). In particular, they will encourage their members to identify appropriate best practice for their operations and commit to operating according to these standards provided that they are technically and economically feasible. As a minimum, this entails operation according to the IPPC BREF Document (European Commission, 2003). *The BREF Document proposes that chlorinated paraffins be substituted* but, where this is not possible, the British Leather Confederation's members would commit to operating to achieving low emissions from relevant processes. If use of MCCPs is found to occur (or begins), leather processors would:

- take action to minimise emissions of MCCPs to air and water from their operations;

- consider opportunities for recovery, recycling and re-use of potential waste material; and
- monitor chlorine content of waste water to monitor and demonstrate progress (BLC, 2003).

The BREF Document also specifies the best available techniques (BAT) to be used in treatment of water effluent. In terms of measures appropriate for control of MCCP emissions, these include use of mechanical treatment, biological treatment and post-purification sedimentation and sludge handling (these may be on or off site).
Based on the estimate that MCCPs are used in around 3.5% of leather produced in the EU (see Section 1), MCCPs could be used in perhaps 85 companies, assuming that MCCPs are exclusively used in Italy and that the percentage of companies using MCCPs is proportional to the percentage of leather in which MCCPs are used. If these companies were required to introduce additional emissions abatement equipment, the costs could be significant.

Plants for the tanning of hides and skins where the treatment capacity exceeds 12 tonnes of finished products per day come under the IPPC Directive.
There is some variation between Member States on the extent of IPPC coverage within the sector:

- Sweden & the Netherlands have decided to apply IPPC to all tanneries regardless the production capacity
- In the UK only tanneries deemed to be above the 12 tonnes per day threshold are subject to IPPC, the others are under separate controls. It is expected that only 4 of about 40 will fall under the Directive.
- In Spain out of 223 tanneries only 3-5 will fall under the directive (however, because of BAT criteria, and the requirement to develop an Environmental Evaluation, 91 tanneries are currently affected).
- In Italy, the largest tanning country in Europe only about 10 should fall under the scope of IPPC.
- In France out of 100 tanneries and dressers, none will fall under the directive[79].

The EU IPPC BREF guidance does not provide any specific information on potential control measures for smaller, non-IPPC sites in particular. However, it does recommend that exhaustion of fatliquors to the equivalent of 90% of the original offer can be considered achievable, together with the selection of fatliquors not containing either organic solvents or AOX releasing compounds. This may be of relevance to smaller sites where BAT treatment is less economically feasible (UNIC, 2004).

B6.3 Potential Substitutes for MCCPs

It is considered that there are suitable substitutes for MCCPs available for use in leather fat liquors. In particular, alternatives are suggested in the BREF Document for

[79] All bullets sourced from: COTANCE (2002). Workshop on the economic consequences of the IPPC Directive, Brussels, 16 May 2002.

tanneries as part of a need to reduce emissions of adsorbable organic halogens (AOX). A number of potential substitutes are identified in Section 5 of this report, although relatively little information exists regarding the potential risks to the environment of these substances.

In addition, information provided by UNIC (2004) suggests that leather treated with MCCPs are only used in relatively small quantities because they generally are not soft to the touch and leather produced with alternative fat liquoring agents are preferred (e.g. sulpho-chlorinated paraffins).

Another alternative is to use long-chain chlorinated paraffins which are reported to be around 20% more expensive than MCCPs in Italy. Substitution with LCCPs would currently lead to increased costs of chlorinated paraffins of 20%, with an increase in total costs of around 2% for the entire fat liquor. UNIC suggests that this cost be considered significant. The overall cost for the total use of MCCPs would be around €130,000 per year for the total EU use of around 1,300 tonnes per year (assuming that the current price of MCCPs is around €500 per tonne). This represents around 0.002% of the turnover of the Italian leather industry or around 0.0015% of the turnover of the leather industry in the EU-15.

B6.4 Industry Views on Implementing a Risk Reduction Strategy

In the UK, whilst there is reportedly no use of MCCPs, the national trade association has committed to various actions to minimise the environmental risks associated with their releases if and where they are used (see above).

Following the steering group meeting to discuss the findings of Stage 3 in development of this risk reduction strategy, COTANCE was again consulted regarding the conclusion that marketing and use restrictions appear to represent the most appropriate balance of advantages and drawbacks for this sector. A response was provided in which the following was stated (COTANCE, 2004b):

> *"COTANCE understands the need of addressing the risks associated with the use of MCCPs by processing sectors and thus also for consumer products during their lifecycle until disposal.*
>
> *"According to our information, the leather sector in the EU is a marginal user of MCCPs, which it consumes though opportune preparations. The tanning sectors' SMEs are likely to ignore the presence of this substance in their processing chemicals or whether their standard precautionary measures suffice to reduce the associated risks to an innocuous level.*
>
> *It is our understanding that safer alternative substances, although more expensive, are available on the market and are being formulated for their use in the leather industry.*
>
> *COTANCE therefore agrees with risk reduction measures regarding the marketing and use - Directive on the Marketing and Use of Dangerous Substances and Preparations (Directive 76/769/EEC) - of MCCPs in the leather industry combining:*

1. A control of the substance restricting its marketing and use in the leather industry to a level that is considered safe for the environment and consumers of leather articles. This could be enacted by limiting its concentration in preparations intended for the use in the leather industry to a level that is known to be safe in its use and throughout the lifecycle of the leather until the disposal of the leather article;

2. The setting of "no concern" value limits for industrial emissions and for their presence in leather and leather articles sold on the EU market. Preparations containing MCCPs should cross-reference these value limits in their Safety Data Sheets and indicate the necessary precautionary measures for complying with the legal restriction.

3. The reference to an official test method for identifying the presence of MCCPs and determining their accurate concentration in leather and leather articles. If such an analytical method does not exist, it should be developed in order to provide to enforcement authorities in Member States an instrument to guarantee that risks associated with the use of MCCPs in leathers and leather articles bought in the EU are appropriately controlled."

It should be noted that, because the PEC/PNEC ratios for this sector are relatively high – up to around 17 for *use* of MCCPs in leather fat liquors - it is likely that any 'safe' limit for the environment, as prescribed by COTANCE, would preclude the use of MCCPs as an intended component of these preparations. Therefore, specification of such a limit would be equivalent to a prohibition on marketing and use.

In addition, the producers of MCCPs agreed to examine the potential for a voluntary agreement not to use MCCPs among the *formulators* of leather fat liquors (since there are fewer companies involved and hence such an agreement could potentially be simpler to achieve). However, based on the outcomes of this, it does not appear that such an approach could easily be agreed amongst the formulators.

B7 Use in Carbonless Copy Paper

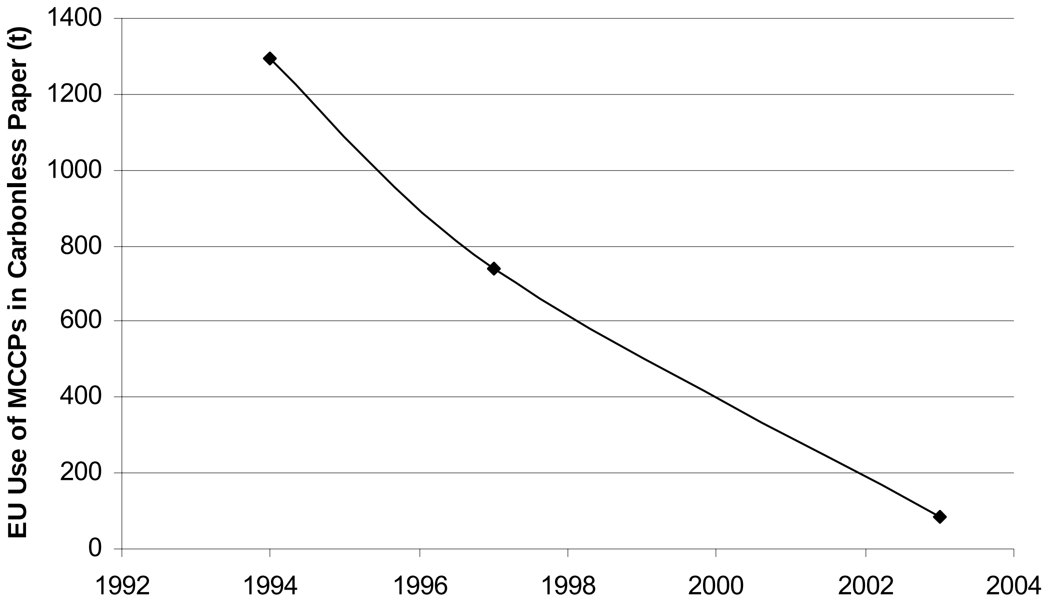
B7.1 Consultation Undertaken

Contact has been made with a number of trade associations in the UK and EU. In particular, the majority of information provided has come from the Association of European Manufacturers of Carbonless Paper.

As detailed in the main report, the AEMCP's voluntary commitment under its Environmental Safety Policy requires that use of MCCPs should be ceased, due to the finding that the PEC/PNEC ratio for this use is greater than unity. Whilst this conclusion was only agreed in 1996 a representative of AEMCP has indicated that MCCPs have not been used by AEMCP members for around 15 years and that members would avoid these materials for marketing reasons. The current concern regarding recycling of materials containing MCCPs would reportedly be a strong factor in the ongoing avoidance of such materials by AEMCP members.

Figure B7.1 provides a summary of sales data for MCCPs used in carbonless paper in the EU. As can be seen, use had declined to less than 100t by 2003 and, as indicated in the main report, use may decline further still as the one company that was reported to be using MCCPs has now gone into administration. If the trend in MCCP use in this sector continues, they may be effectively phased out in this sector.

Figure B7.1 MCCPs Sales for Carbonless Paper in the EU (Cefic, 2004)



There could potentially be a significant quantity of carbonless copy paper currently ‘in circulation’, however. For example, within the past 10 years, it could be expected that around 6,500 tonnes of MCCPs have been used in this application (assuming a linear reduction as in Figure B7.1), equivalent to up to 220,000 tonnes of carbonless paper[80]. It is possible that significant quantities of this paper could remain in use or in storage within offices, for example.

However, the amount of carbonless paper containing MCCPs is relatively small compared to the total amount of paper and card produced each year: in 2003 alone, members of the Confederation of European Paper Industries produced around 95 million tonnes (Cepi, 2004).

Nonetheless, it could be envisaged that a significant quantity of carbonless paper containing MCCPs might be disposed of at one time (e.g. following a large office clear-out), leading to a significant emission to the environment. A possible means of controlling such impacts would be to monitor the inputs to paper recycling plants in the EU. However, this is likely to be impractical given the quantities of paper recycled

[80] Assuming a concentration of 3% MCCP in the carbonless paper (indicated as 3-4% in the risk assessment).

each year. It is not considered to be practical to separate carbonless paper from the general waste paper stream in order to eliminate this source of possible emissions.

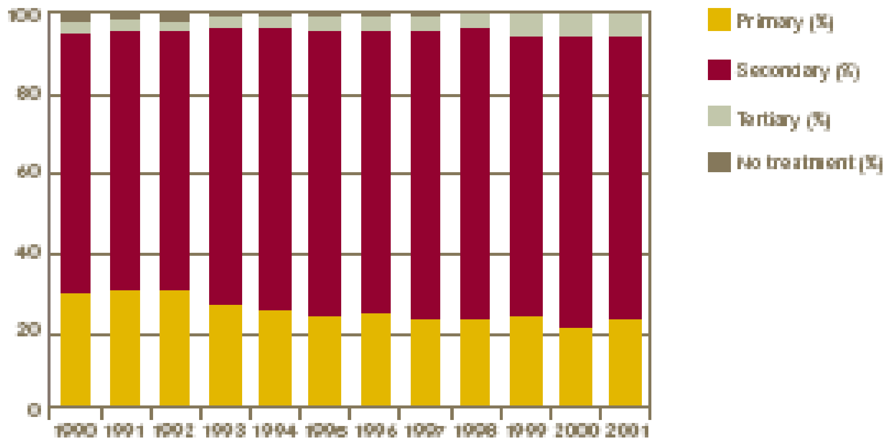
B7.2 Current Controls and Potential for Further Reduction

As carbonless paper is not generally segregated from other types of paper for recycling, the most practicable means of ensuring that any future environmental risks are adequately controlled would be through ensuring that the wastewater treatment at paper mills is sufficient to remove MCCPs.

Nearly all paper mills in Europe have a minimum of primary wastewater treatment installed (EU IPPC/BREF note). Over 95% of effluents from the pulping and papermaking processes are treated either by primary or secondary treatment methods (CEPI, 2002). Wastewater in the European paper industry is to a great extent discharged directly to surface water bodies after primary and biological treatment, or to a municipal wastewater treatment plant, following clarification for suspended solids removal.

Secondary treatment is commonly biological and in some cases, secondary chemical precipitation or flocculation of wastewater is applied (although mainly at smaller mills). Tertiary treatment is most likely to be applied where recycling of process water takes place or if the mill discharges to very sensitive recipients. Advanced wastewater treatment in the pulp and paper industry is mainly focused on additional biological membrane-reactors; membrane filtration techniques such as micro-, ultra or nano-filtration; ozone treatment and evaporation. Due to relatively less full-scale experience, sometimes relatively high capital and operating costs and increased complexity of the water treatment, there are only a few full-scale applications of tertiary treatment of wastewater mill effluent up to now (EU BREF). In most cases where tertiary treatment is applied, it is simply chemical precipitation.

Figure B7.2 Effluent treatment methods in the European pulp and paper industry, data cover 42% of the production of market products (CEPI, 2002)



The potential for reduction of MCCPs to an acceptable level of risk could most likely achieved by introducing secondary and possibly tertiary treatment where primary only currently exists. According to CEPI (2002) and as indicated in Figure B7.2, the level of effluent from paper mills that is treated at the primary level only is around 24%. In order to reduce the highest PEC/PNEC ratio of 51.8 (secondary poisoning in the earthworm food chain) to below 1, it would be necessary to achieve a reduction in post-primary treatment emissions of over 98%. By introducing secondary treatment to all sites that do not currently have it in place, it could be possible to significantly reduce the risks by removing around 95% from effluent (reducing the PEC/PNEC ratio to around 2.6. Whilst this would not completely eliminate the identified need for limiting the risks, it would significantly reduce the level of concern.

An aerobic activated sludge unit (around 95% efficient at effluent removal) with capacity of 5000m^3/day amounts to a total capital cost of around €6.5 million and an operating cost per year of around €137,000 (Defra, 1999). Table B7.1 presents cost estimations for installation of secondary waste water treatment resulting in a total capital cost of around €981 million. If annualised over ten years using the interest and discount rate assumptions in Table B7.1, this would result in a total annualised cost of around €137 million. Thus, the costs for this measure would be very significant and would not necessarily remove the identified need for limiting the risks.

Table B7.1 Estimated Costs for Installation of Secondary Water Treatment at Paper Mills

Total paper production treated only to primary (tonnes) [1]	22,800,000
Total annual water use (m3) [2]	255,360,000
Average daily water use/treatment capacity (m3/day)	700,000
Total capital cost (€m) [3]	981
Total annual operating cost (€m)	19.2
Total annualised cost (€m)	137

[1] Equivalent to the tonnage of paper production assumed to have only primary effluent treatment (24% of total paper production - 95 million tonnes)

[2] Assuming average 11.2 m^3/tonne - suggested average water effluent per tonne paper produced from: http://www.paperloop.com/db_area/archive/ppi_mag/2003/0312/02.html. The EU IPPC Bref (page 239) note suggests a range of 5-20 m3/tonne for recycling of writing and printing paper, less 1.5 m3/tonne due to evaporation.

[3] Assuming costs equivalent to installing 5000 m^3/day plants (€ 6.512m). Assuming capital costs are covered by a loan, repaid over 10 years at 6% interest rate, each future payment is then discounted at 3.5% discount rate.

Figures have been rounded.

As figures on onsite treatment facilities were available for general paper mills only, it has been assumed that similar proportions with only primary onsite treatment also apply for recycled paper plants. It is also assumed that average costs per m^3 capacity would be equivalent to installing 5000 m^3/day capacity plants to cover the additional treatment. However, it has been suggested that sites where recycling of paper takes place are more likely to have secondary treatment in place due to the additional emissions occurring through the de-inking process. Therefore, the costs could potentially be significantly lower than those included here. Nonetheless, given the current small usage of MCCPs in this application and given that the costs would still be expected to be significant, it is unlikely to be appropriate to recommend requiring these controls on the basis of this substance alone. Whether such controls should be introduced due to wider concerns on emissions from these sites is not considered in this report.

B7.3 Potential Substitutes for MCCPs

Whilst no companies currently using MCCPs in carbonless paper have been identified, potential substitute solvents for use in the microcapsules utilised in carbonless paper have been identified in the literature and include:

- Benzylated ethylbenzene;
- Benzyl butyl phthlate;
- Isopropylbiphenyl; and
- Diisopropylnaphthalene (Thies, 1995).

Consultation undertaken for this risk reduction strategy suggests that companies that had used MCCPs in the past did so primarily on the basis of price: the least expensive solvent suitable for the application would be chosen and so companies would alternate between using MCCPs and alternatives. Given the variation in prices of such chemicals over time, it is assumed herein that there is no cost penalty associated with using alternatives in the long term.

No consideration was given in developing this risk reduction strategy to the suitability of substitutes for MCCPs in risk terms because substitution has already taken place outside the scope of this strategy.

B7.4 Industry Views on Implementing a Risk Reduction Strategy

The AEMCP (representing over 95% of EU-based producers) has in place a commitment that members will not use MCCPs in their products, through a general commitment not to use substances that pose a risk to the environment. This is believed to have been the significant driver in the reduction of use in this application (and the consequent reduction in risks to the environment).

Appendix C
Possible Substitutes for MCCPs (Hazard Data and Physicochemical Properties)

This appendix provides some key data on the physicochemical properties, environmental hazard data and expected classification and labelling requirements[81] under Directive 67/548/EEC. The following substances are included (and data provided for MCCPs for comparison):

- Long chain chlorinated paraffins;
- Cresyl diphenyl phosphate (CDP);
- Tricresyl phosphate (TCP);
- Triphenyl phosphate (TPP);
- Trixylenyl phosphate (TXP);
- Isopropylated phenyl phosphates (IPP);
- 2-Ethylhexyl diphenyl phosphate (ODP);
- Isodecyl diphenyl phosphate (IDDP).

All of these substances have been identified as potential substitutes for MCCPs in PVC, other polymers and a number of other applications.
Sources are Environment Agency (2004) for MCCPs; Environment Agency (2004a) for phosphate esters; and Environment Agency (2001) for LCCPs.

[81] Expected classification and labelling where proposed classification has been developed (Environment Agency, 2004a) in draft form but not yet formally proposed.

Table C1a Comparison of MCCPs with Some Possible Alternatives (Physicochemical Properties and Environmental Hazard Data)

Name	MCCPs	Cresyl diphenyl phosphate (CDP)	Tricresyl phosphate (TCP)	Triphenyl phosphate (TPP)	Trixylenyl phosphate (TXP)
CAS Number	85535-85-9	26444-49-5	1330-78-5	115-86-6	25155-23-1
EINECS Number	287-477-0	247-693-8	215-548-8	204-112-2	246-677-8
Melting point	-45 to 25 °C (pour point)	-35°C (pour point)	-30°C (pour point)	49°C	-20°C
Boiling point (at atmospheric pressure)	>200oC	390°C at 101.3 kPa	>300°C	370-500°C	>300°C
Relative density	1.1 to 1.3 (20/60°C)	1.21 at 25°C	1.16-1.17 at 20°C	1.185-1.202 at 25°C	1.13-1.14 at 20°C
Vapour pressure	2.7×10^{-4} at 20 °C	3.3×10^{-5} Pa at 20°C or 6.3×10^{-5} Pa at 25°C	3.5×10^{-5} Pa at 20°C and 6.6×10^{-5} Pa at 25°C	2.4×10^{-3} Pa at 20°C or 4.1×10^{-3} Pa at 25°C [3]	8.7×10^{-6} Pa at 20°C
Water solubility (at room temperature)	0.027 mg/l	2.6 mg/l	0.36 mg/l	1.9 mg/l	0.89 mg/l
Octanol-water partition coefficient (log value)	5.52 to 8.41 (7 in RAR)	4.51	5.11	4.63	5.63
Henry's law constant (Pa m^3/mole)		4.3×10^{-3} at 20°C and 8.2×10^{-3} at 25°C	0.036 at 20°C and 0.068 at 25°C	0.21 at 20°C and 0.41 at 25°C	0.0040 at 20°C
Flash point	>210°C	>220 to >242°C	225-410°C	>220°C	>220°C
Autoignition temperature	Not stated	>500°C	>500°C	No data available	566-575°C
Explosivity	Not applicable	No data located	No data available	No data available	Not explosive
Current environmental classification	None	N: R51/53 [2]	N: R51/53	N: R50/53	None
Proposed environmental classification	N: R50/53 [1]	N: R50/53	N: R50/53	N: R50/53	N: R51/53

[1] Classification as R50/53 has been agreed by the Committee on the Classification and Labelling of Dangerous Substances.
[2] One product classified by manufacturer as N: R50/53.
[3] Values are for sub-cooled liquid. Values for solid are: 1.2×10^{-3} Pa at 20°C or 2.4×10^{-3} Pa at 25°C.

Table C1b Comparison of MCCPs with Some Possible Alternatives (Physicochemical Properties and Environmental Hazard Data) (continued)

Name	IPP [1]	ODP	IDDP	LCCPs
CAS Number	Various [2]	1241-94-7	29761-21-5	85422-92-0 & 63449-39-8
EINECS Number	Various [2]	214-987-2	249-828-6	287-196-3 & 264-150-0
Melting point	-26°C	-60°C (pour point)	<-50°C (pour point)	Various
Boiling point (at atmospheric pressure)	>300°C	375°C	>245°C (decomposes)	>200°C
Relative density	1.1 to 1.2 at 25°C	1.07-1.09 at 20°C	1.07-1.09 at 20°C	1.1 to 1.63
Vapour pressure	2.3×10^{-6} to 9.5×10^{-6} Pa at 25°C	3.4×10^{-4} Pa at 20°C and 6.2×10^{-4} Pa at 25°C	3.6×10^{-5} Pa at 20°C	$2.67x10^{-3}$ Pa at 20°C
Water solubility (at room temperature)	0.12-2.2 mg/l	0.38-1.9 mg/l	0.03-0.75 mg/l	0.03-0.06 mg/l
Octanol-water partition coefficient (log value)	5.3 to 6.1	5.73	5.44	7.5-12.8
Henry's law constant (Pa m^3/mole)	0.0016 to 0.0087 at 20°C	0.065/0.12 at 20/25°C	0.019 at 20°C	Various
Flash point	>200°C	224°C	240°C	>210°C
Autoignition temperature	>551-585°C	>500°C	260°C	Not stated
Explosivity	No data available	No data available	No data located	Not applicable
Current environmental classification	N: R51/53 (15-25% TPP) N: R50/53 (>25% TPP) [3]	None	None	None
Proposed environmental classification	N: R50/53 [3]	N: R50/53	N: R50/53	No formal proposal [4]

[1] Various values for different IPP derivatives quoted. Ranges are quoted here.
[2] For isopropylphenyl diphenyl phosphate, tris(isopropylphenyl) phosphate and Phenol, isopropylated, phosphate (3:1) the CAS/EINECS Numbers are 28108-99-8 / 248-848-2, 26967-76-0 / 248-147-1 and 68937-41-7 / 273-066-3.
[3] Those with <10% triphenylphosphate (TPP) are not classified as dangerous to the environment. The proposed classification relates to these products.
[4] However, it was stated that reclassification of MCCPs as R50/53 could have some impact on the classification of the C_{18-20} LCCPs in particular.

Appendix D
Key Data from Risk Assessment

Table D1 Summary of Key Data from Risk Assessment (ECB, 2005) (based on 1997 usage data)

Use	Use in 1997 (t)	Description of End Uses	Release Scenario [1]	Basis of Emission Estimate
Production		-	Site A	Site-specific data
		-	Site B	Site-specific data
		-	Site C	Site-specific data
		-	Site D	Site-specific data
PVC	51,827	Secondary plasticiser/flame retardant. Used in coatings, flooring, garden hose, shoe compounds (40-45% Cl) and in calendered flooring, cable sheathing/insulation and general purpose PVC (50-52% Cl). Assumed 744t, 3990t and 341t PVC processed per year at open, partially open and closed systems. 10% MCCP assumed for coating processes and 15% for extrusion/other processes.	Plastisol coating - Compounding - O	Loss to waste water via spillage during raw materials handling based on 'use category document'.
			Plastisol coating - Conversion - O	Loss during spread coating (flooring, wallcoverings, tarpaulins, etc.) initially to air then half assumed to settle and be washed to waste water (loss to air based on volatility comparison with di-ethylhexyl phthalate).
			Plastisol coating - Compounding/conversion - O	Sum of losses from compounding and conversion
			Extrusion/other - Compounding - O	Loss to waste water via spillage during raw materials handling based on 'use category document'. Plus loss during dry blending, initially to air then half assumed to settle and be washed to waste water (loss to air based on volatility comparison with di-ethylhexyl phthalate).
			Extrusion/other - Compounding - PO	As for Open processes
PVC (continued)			Extrusion/other - Compounding - C	As for Open processes
			Extrusion/other - Conversion - O	Based on calendering process, assuming open system with air emission control. Loss initially to air then half assumed to settle and be washed to waste water (loss to air based on volatility comparison with di-ethylhexyl phthalate).
			Extrusion/other - Conversion - PO	Based on extrusion process, assuming partially-open system with air emission control. Loss initially to air then half assumed to settle and be washed to waste water (loss to air based on volatility comparison with di-ethylhexyl phthalate).

Use	Use in 1997 (t)	Description of End Uses	Release Scenario [1]	Basis of Emission Estimate
			Extrusion/other - Conversion - C	Based on injection moulding or extrusion process, assuming closed system with air emission control. Loss initially to air then half assumed to settle and be washed to waste water (loss to air based on volatility comparison with di-ethylhexyl phthalate).
			Extrusion/other - Compounding/conversion - O	Sum of losses from compounding and conversion
			Extrusion/other - Compounding/conversion - PO	Sum of losses from compounding and conversion
			Extrusion/other - Compounding/conversion - C	Sum of losses from compounding and conversion

Use	Use in 1997 (t)	Description of End Uses	Release Scenario [1]	Basis of Emission Estimate
Metal working/ cutting	5,953	Oil-based and water-based metalworking fluids used in cutting, grinding and forming operations.	Formulation	Assumed 100 t/yr used at any one site. Emission estimate based on 'use category document'.
			Use in oil-based fluids (large facility)	Assumes reprocessing of swarf. Total loss to wastewater estimated at 4% per year (1% from overalls, 1% from leaks, 1% from dragout on the workpiece and 1% from internal reprocessing). Assumes use of 50,000 l/yr of cutting fluid at 5% MCCP concentration.
			Use in oil-based fluids (small facility)	Assumes no swarf reprocessing. Total loss to wastewater estimated at 18% (2% from overalls, 3% from leaks, 1% from dragout on workpiece plus other losses due to settling of losses to air and subsequent losses, as well through line flushing, etc. during external reprocessing). Assumes use of 10,000 l/yr of cutting fluid at 5% MCCP concentration.
			Use in emulsifiable fluids	Assumed 1000 l/week of fluid lost (with 2.5kg MCCP), of which 6% lost to waste water (2% from overalls, 3% from leaks, 1% from dragout on workpiece).
			Use in emulsifiable fluids - intermittent release	Disposal of entire 10,000l of fluid at a site 2-6 times per year (to waste water)
Paints, adhesives and sealants	3,541	Adhesives and sealants (assumed 2,360 t/yr) - plasticiser/flame retardant in e.g. polysulphide, polyurethane, acrylic and butyl sealants for building and construction and double-glazed windows.	Formulation and use	Sealants/adhesives - negligible release assumed based on data provided by UK sealant manufacturers.
		Paints and varnishes (assumed 1180 t/yr) - plasticiser in (mainly) chlorinated rubber-based paints for aggressive marine and industrial environments and vinyl copolymer-based paints for protection of exterior masonry.	Formulation	Formulation - assumed 15 t/yr used at a site (five times average in UK) with emissions to air and surface water based on TGD.
			Industrial application	Industrial application (processing) - based on TGD defaults based on an estimated use of 17.7 t of MCCP in paint at one site.
			Domestic application	Application by general public (private use) - based on assumed fraction in domestic applications and emission factors from TGD.

Use	Use in 1997 (t)	Description of End Uses	Release Scenario [1]	Basis of Emission Estimate
Rubber/polymers (other than PVC)	2,146	Rubber - plasticiser with flame retardant properties for conveyor belts and automotive applications. Plastics - flame retardant plasticisers.	Compounding	Compounding site (formulation) - based on 'Use Category Document', assuming releases direct to waste water plus half of release to air also released to waste water upon condensation.
			Conversion	Conversion site (processing) - same approach as for compounding.
			Compounding/conversion	Combined compounding and conversion site - same approach as for compounding.
Leather fat liquors	1,048	Used at c. 10% by weight to provide light-fastness, low migration and dry surface feel/suppleness.	Formulation	Based on TGD defaults
			Use - complete processing of raw hides	Estimated 15 t/yr use at a site based on TGD but only 25% of this processed using MCCPs. Emission estimates based on generic data provided by industry.
			Use - processing of wet blue	Estimated 15 t/yr use at a site based on TGD. Emission estimates based on generic data provided by industry.
Carbonless copy paper	741	Solvent (non-members of AEMCP only). Applications may include delivery dockets, credit card slips, business forms.	Paper recycling	Based on emission scenario document in TGD. Assumed 50% recycling rate for paper, recycling at 10 sites in EU and 90% removed through primary sedimentation.
Regional sources				
Total	65,256			

[1] O = open process; PO = partially open; C = closed process.

[2] Incorporates measured regional concentration for surface water/soil as appropriate. Secondary poisoning relates to effects in the higher members of the food chain, either living in the aquatic or terrestrial environment, which result from ingestion of organisms from lower trophic levels that contain accumulated substances.

Table D2 Extrapolated regional and total EU emissions for 2006 (Environment Agency, 2008)

Scenario	Emissions reported in EU (2005) – 1997 data (kg/year)		Extrapolated emissions for 2006 (kg/year)	
	Regional	Total EU	Regional	Total EU
Production	65 to waste water	65 to waste water 37 to surface water	65 to waste water	65 to waste water 37 to surface water
PVC - compounding	869 to waste water 351 to air	8,686 to waste water 3,506 to air	333-523 to waste water[5] 21.1-211 to air[5]	3,331 to waste water[5] 211-2,110 to air[5]
PVC - conversion	10,215 to waste water 10,215 to air	102,150 to waste water 102,150 to air	615 to waste water[5] 615 to air[5]	6,153 to waste water[5] 6,153 to air[5]
Use in rubber/plastics - compounding	32.3 to waste water 10.8 to air	323 to waste water 108 to air	96 to waste water 32 to air	959 to waste water 319 to air
Use in rubber	108 to waste water 108 to air	1,074 to waste water 1,074 to air	321 to waste water 321 to air	3,187 to waste water 3,187 to air
Sealants and adhesives[2]	negligible	negligible	negligible	negligible
Paints and varnishes[2] - formulation	354 to waste water 118 to air	3,540 to waste water 1,180 to air	1,019 to waste water 340 to air	10,191 to waste water 3,397 to air
Paints and varnishes[2] – industrial application of paints	118 to waste water	1,180 to waste water	340 to waste water	3,397 to waste water
Metal cutting/working fluids - formulation	1,488 to waste water	15,363 to waste water	[2,229 to waste water][6]	[23,012 to waste water][6]
Metal cutting/working fluids – use in oil-based fluids	38,100 to waste water	381,000 to waste water	[57,070 to waste water][6]	[570,700 to waste water][6]
Metal cutting/working fluids – use in emulsifiable fluids	99,200 to waste water	992,000 to waste water	[148,592 to waste water][6]	[1,485,917 to waste water][6]
Metal cutting/working fluids – recovery/recycling	not included	not included	436 to waste water[5]	4,364 to waste water[5]

Scenario	Emissions reported in EU (2005) – 1997 data (kg/year)		Extrapolated emissions for 2006 (kg/year)	
	Regional	Total EU	Regional	Total EU
Leather fat liquors - formulation	315 to waste water 105 to air	3,150 to waste water 1,050 to air	191 to waste water 64 to air	1,911 to waste water 637 to air
Leather fat liquors - processing	1,050 to waste water	10,500 to waste water	638 to waste water	6,370 to waste water
Carbonless copy paper - recycling	3,705 to waste water	37,050 to waste water	0 to waste water	0 to waste water
Service life - PVC	2,590 to waste water 2,590 to air	25,900 to waste water 25,900 to air	1,560 to waste water 1,560 to air	15,596 to waste water 15,596 to air1
Service life – rubber/polymers	107 to air	1,070 to air	318 to air	3,176 to air
Service life – paints[2]	1,240 to waste water 3,300 to air	12,400 to waste water 33,000 to air	3,570 to waste water 9,500 to air	35,697 to waste water 95,000 to air
Service life - adhesives and sealants[2]	10,600 to waste water 118 to air	106,000 to waste water 1,180 to air	30,515 to waste water 340 to air	305,154 to waste water 3,397 to air
Waste remaining in the environment - PVC	16,600 to waste water 22,050 to surface water 90 to air 66,200 to urban/industrial soil	166,000 to waste water 220,500 to surface water 900 to air 662,000 to urban/industrial soil	9,996 to waste water 13,278 to surface water 54 to air 39,864 to urban/industrial soil	99,961 to waste water 132,780 to surface water 542 to air 398,641 to urban/industrial soil
Waste remaining in the environment – rubber/polymers	2,120 to surface water 8 to air 6,360 to urban/industrial soil	21,200 to surface water 80 to air 63,600 to urban/industrial soil	6,292 to surface water 24 to air 18,876 to urban/industrial soil	62,918 to surface water 237 to air 188,755 to urban/industrial soil
Waste remaining in the environment – paints[2]	2,730 to surface water 11 to air 5,650 to urban/industrial soil	27,300 to surface water 110 to air 56,500 to urban/industrial soil	7,859 to surface water 32 to air 16,265 to urban/industrial soil	78,592 to surface water 317 to air 162,653 to urban/industrial soil

Scenario	Emissions reported in EU (2005) – 1997 data (kg/year)		Extrapolated emissions for 2006 (kg/year)	
	Regional	Total EU	Regional	Total EU
Waste remaining in the environment – sealants and adhesives[2]	5,470 to surface water 22 to air 16,480 to urban/industrial soil	54,700 to surface water 220 to air 164,800 to urban/industrial soil	15,747 to surface water 63 to air 47,443 to urban/industrial soil	157,471 to surface water 633 to air 474,428 to urban/industrial soil
Total not including waste remaining in the environment[3, 4]	**170,049 to water (spilt 136,039 to waste water and 34,010 to surface water)** **17,023 to air**	**1,700,392 to water (split 1,360,284 to waste water and 340,108 to surface water)** **170,216 to air**	**39,889 to water (spilt 31,911 to waste water and 7,978 to surface water)** **13,299 to air**	**398,312 to water (split 318,620 to waste water and 79,692 to surface water** **132,973 to air**
Total including waste remaining in the environment[3, 4]	**219,019 to water (split** **149,319 to waste water and 69,700 to surface water)** **17,154 to air** **94,690 to urban/ industrial soil**	**2,190,092 to water (split 1,493,084 to waste water and 697,008 to surface water)** **171,526 to air** **946,900 to urban/ industrial soil**	**92,061 to water (split 39,908 to waste water and 53,153 to surface water)** **13,472 to air** **122,448 to urban/ industrial soil**	**930,034 to water (split 398,589 to waste water and 531,445 to surface water)** **134,703 to air** **1,224,447 to urban/ industrial soil**

Notes:
1 - Based on Environment Agency (2008).
2 - ECB (2005) assumes that the usage in paints, sealants and adhesives is split two thirds sealants and adhesives to one third paints. The same assumption has been used here. However it should be noted that the 2006 data are for sealants and adhesives only and it is not clear if this figure also includes paints and other coatings.
3 - The calculations in ECB (2005) were carried out both with and without waste remaining in the environment.
4 - In ECB (2005) a 70% connection rate to waste water treatment plants was assumed (an earlier version of EUSES was used in the calculation). An 80% connection rate has been assumed here in line with the approach included in EUSES v2.0.3).
5 - Estimated in Environment Agency (2008) (Section 2 and Section 3).
6 - The risk reduction measures being considered for metal working fluids (for human health) would lead to a marked reduction in the emissions to the environment from these sources. For this analysis these emissions have not been considered in the total regional and continental emissions.

Appendix E
Text on possible considerations related to any precautionary action to restrict use of MCCPs

This appendix provides information from the February 2008 draft of this risk reduction strategy (presented at the 15th risk reduction strategy meeting) regarding factors that may be taken into account in any precautionary decision to adopt wider restrictions on MCCPs.

In considering whether such precautionary action is appropriate, the following factors should be taken into account.
Firstly, there are concerns highlighted in the risk assessment, particularly in relation to the presence of the substance in marine biota and the apparent persistence of the substance.

Secondly, in relation to concerns regarding PBT properties, not only the uses where a need for limiting the risks based on PEC/PNEC ratios need to be taken into account but also all other uses, including in addition waste remaining in the environment and releases during the service life of products.

Thirdly, for sectors other than use in leather fat liquors, it was concluded in this strategy that marketing and use restrictions are not the most appropriate option and that the drawbacks of such a measure outweigh the advantages *on the basis of the risks identified using the PEC/PNEC approach.* This is based on the following factors described in Section 5 of this report:

- For several sectors, the available alternatives may not pose significantly lower risks for the environment. This applies to several of the potential substitutes for use in metalworking fluids, PVC and rubber/other polymers;
- There appear to be no suitable substitutes for chlorinated paraffins in technical terms for a number of uses of MCCPs, particularly in the most arduous metalworking operations. It would therefore be essential for any marketing and use restrictions to include derogations if significant technical and economic implications are not to be imposed upon industry (and ultimately consumers);
- Not all of the identified installations will contribute significantly to environmental concentrations given that the processes (and emission controls) employed will limit emissions to the environment; and
- For several sectors, the cost of substitution is considered to be disproportionate, particularly given the above considerations regarding the availability and suitability of substitutes.

Fourthly, the risk assessment recommended that "consideration could be given at a policy level to the need to investigate precautionary risk management options now in the absence of measured environmental half-life data and confirmatory bioaccumulation data, to reduce the inputs to water (and soil from the application of sewage sludge), including from waste remaining in the environment". The measures proposed to address the risks on the basis of the PEC/PNEC ratios are indeed intended to address inputs to water (and soil from the application of sewage sludge). However, they do not address the potential risks associated with waste remaining in the environment.

Finally, it was also pointed out in the risk assessment that the assessment of secondary poisoning leads to the identification of risks from several uses of MCCPs and that a key consideration is therefore whether or not there is any added concern for medium-chain chlorinated paraffins over and above that already identified based on a PEC/PNEC approach, given that the PEC/PNEC approach already considers that uptake into aquatic organisms may occur from both exposure via water and via food[82]. The measures proposed to address the risks identified on the basis of the PEC/PNEC approach are already intended to address these secondary poisoning endpoints.

[82] Factors such as the bioconcentration factors for MCCPs and very long apparent depuration half-life that has been found in mammalian systems also need to be taken into account. These may introduce uncertainties into the risk assessment of secondary poisoning when extrapolating from the results of laboratory tests to PECs and PNECs related to exposure over an organism's lifetime.