05.11.10

Impact assessment of regulation of medium-chain chlorinated paraffins C_{14-17} (MCCPs) in consumer products

Summary

The Norwegian Government is proposing to regulat the production, import, export and sales of consumer products containing medium-chain chlorinated paraffins C_{14-17} (MCCPs) when the contents of the substance in the product's homogenous individual parts are higher or equal to 0.1% by weight. This proposal does not cover products with special flame retardant (fire safety) requirements and where there are no satisfactory alternatives.

The Norwegian Government has established national targets for eliminating or substantially reducing releases of priority hazardous substances by 2010 with a view to eliminating them by 2020, (Prop. 1 S (2009-2010) from the Norwegian Ministry of the Environment, Proposition to the Parliament (Storting) for the 2010 budget year) The substances included in

this target are given in the Governments list of hazardous substances (the Priority List). MCCPs are one of the substances on this list.

Medium-chain chlorinated paraffins (MCCPs) are used as softeners and flame retardants and are especially found in products such as rubber and PVC, which are subsequently used in the production of cables, floor coverings and miscellaneous consumer products. MCCPs are barely used in Norwegian manufacturing but they are present in products imported from the EU and other countries.

MCCP consumption and discharge figures show that 'products' as a group constitute the largest usage area and the greatest potential for dispersion into the environment. Calculations based on EU data indicate that about 640 tones of MCCPs were marketed in 2006, and that there has barely been any reduction in the consumption and discharge from 1995 to 2006.

MCCPs do not occur naturally in the environment. However, a significant quantity of MCCPs have been detected in the Norwegian environment, both in biological materials and in sediments from freshwater and marine environments (among others, in Mjøsa, the largest lake in Norway, which is an important source of drinking water). MCCPs are discovered in leachate from waste disposal sites, and soil and sediment samples from disposal sites show that products constitute a significant source of MCCP discharges into the environment. Additionally, MCCPs have also been detected in sediments in the Arctic, which indicates a potential for long-range transport.

MCCPs are classified as "Very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment" and it is suggested to be assigned the risk phrase "May cause harm to breast-fed babies" in the EU's technical adaptation to the new regulation on classification, labelling and packaging of substances and mixtures (1st Adaptation to Technical Progress (ATP) to Classification, Labeling and Packaging (CLP). MCCPs are measured in the environment and have been detected in breast milk, cow's milk, some marine fish and marine mammals. Absorption of MCCPs via food is important, since higher values are found than what one would expect from the bioconcentration levels.

The documentation shows that some MCCP components have Persistent, Bioaccumulative and Toxic (PBT) properties, which means they are toxic, they bioaccumulate and they are persistent in the environment. Because MCCPs are a potential PBT substance, acceptable concentration levels of such substances in the environment cannot be established with certainty. The key problem is the general dispersion of MCCPs into the environment from a great variety of products throughout their entire lifecycle, through usage and as waste. This particularly applies to rubber and plastic products, including PVC where the discharge can be significant. MCCPs in products are not converted during the service life; the entire quantity used in products may leak out into the environment through use or when the product ends up as waste. The dispersion of substances that are persistent and are stored in living organisms constitutes a special problem because accumulation in the environment is difficult to reverse and the long-term effects can be difficult to predict. This is a critical issue that justifies the need for measures.

Consumer products are an important source of uncontrolled dispersion of priority substances into the environment. Consumer products are particularly important since consumers lack the requisite knowledge about the health-related and environmental problems associated with

their use and the disposal of these substances as waste. Consumers also do not have the requisite knowledge and ability to protect themselves against the emissions. The entire population, including vulnerable groups such as children, is therefore exposed to discharges and emissions from consumer products, either directly or indirectly via the environment.

Where MCCPs are only used as softener, there are several alternatives that both meet the technical properties and have less serious health and environmental properties. For many of the relevant PVC products where MCCPs are used as softener, there are alternative materials with elastic properties without the addition of softener. There are alternatives for flame retardants; however, there is not the same selection as for softeners. They are more expensive and several of the relevant alternatives also have environmental properties that give cause for concern. The proposal therefore does not cover products with special requirements for flame-retardant (fire- safety) and where there are no satisfactory alternatives.

The regulatory proposal may result in somewhat increased costs but will bring about a significant reduction in the introduction of MCCPs into the environment and will reduce the risk of health damages. Seen in relation to the effects on human health and the environment of MCCPs and properties of the alternatives, we believe that the increased costs are acceptable. The proposal will have a positive impact on companies producing alternatives. Overall, our assessment is that the measure will not result in significant socioeconomic costs. We are anticipating that the benefits will outweigh the costs on the basis of the expected positive effects the proposal will have for health and the environment. The proposal makes exceptions for uses where no alternatives exist or where these involve significant costs.

1 Background and Previous Process

1.1 Background

Medium-chain chlorinated paraffins $C_{14\text{-}17}$ (MCCPs) covered by the proposed regulation are priority substances and among some of most dangerous substances we know. The effects of these types of hazardous substances are very serious because they are persistent; they bioaccumulate and/or are toxic (for example, they cause harm to the reproductive system and are carcinogenic). This means that the effects must be deemed irreversible. Priority substances are a serious threat to the health of future generations, to the environment and future food safety. Ecological toxins accumulate in nature and in the food we eat and possess properties that make it too late to take measures once the damage is done.

The Norwegian Government has established national targets for eliminating or substantially reducing releases of priority hazardous substances by 2010 with a view to eliminating them by 2020, (Prop. 1 S (2009-2010) from the Norwegian Ministry of the Environment, Proposition to the Parliament (Storting) for the 2010 budget year) The substances included in this target are given in the Governments list of hazardous substances (the Priority List). MCCPs are one of the substances on this list The efforts to reach these targets are based on the implementation of initiatives to address identified threats from chemicals hazardous to health and the environment even if the scientific data may not yet be fully documented. Regulation to reduce or eliminate use and release of chemicals hazardous to health and the environment is based on existing knowledge about the health and environmental properties of chemicals and the effects these may have in the short and long terms. This knowledge must be seen in the context of society’s needs to protect health and the environment. The precautionary principle entails that, once a specific threat against health and the environment

from chemicals has been identified, measures must be implemented to reduce or eliminate the threat even if the knowledge remains uncertain.

Products are an important source of discharges and emissions in Norway. Consumer products containing MCCPs are particularly important since consumers lack the requisite knowledge about the health-related and environmental problems associated with their use and their disposal as waste. Consumers also do not have the requisite knowledge and ability to protect themselves against the emissions. The entire population, including vulnerable groups such as children, is therefore exposed to exposure from emissions from consumer products, either directly or indirectly via the environment. Reducing the quantity of MCCPs in products is also an important step toward reducing the quantity of hazardous waste that is generated. Consumer products are an important source of uncontrolled dispersion of MCCPs into the environment. Compared to other products containing MCCPs, consumer products can result in a particularly high degree of diffuse dispersion.

The strong increase in sales of consumer products, with the greater selection and shorter lifetime of products, may increase the dispersion of MCCPs. It is not the intention of most products to release the substance during use. However, there are several examples that chemical substances can spread from goods, so that discharges are spread out over time (the product's entire life cycle) and space (people are exposed indirectly via the environment). For example, leaks from polymer materials or the maintenance of goods, e.g. washing, can result in the dispersion of MCCPs from products. Contrary to industrial point sources, diffuse discharges from products are more spread out throughout society. The knowledge about the mechanisms and the scope of diffuse emission from products is lacking.

The increased dispersion of MCCPs released from products into the environment results in human exposure by breathing, drinking or by absorbing the substance through the skin. Dispersion of persistent substances stored in living organisms constitutes a special problem because the substances take a very long time to be reduced to a level that does not involve risk of damage. MCCPs are just one of many health and environmentally hazardous substances, which, together with other similar substances, contribute to exposing consumers to a variety of many different substances. The knowledge about the synergistic effects, i.e. how people and the environment are affected by exposure to several substances at the same time, is lacking.

The most effective manner in which to limit problems associated with a substance present in a number of different products is to regulate it as close to the source as possible and as early in the supply chain as possible. It is much more difficult to take steps to prevent uncontrolled dispersion of MCCPs at some later point in time after the products have already been put on the market. We therefore believe that the proposal to regulate MCCPs in consumer products fulfils the general principles of risk management.

The health and environmental effects of MCCPs will take many years to show. It is therefore crucial that the risk associated with the use of products containing MCCPs should be limited, especially because monitoring data show that the substance is recovered in the Norwegian environment. In order to limit the risk, we believe it is necessary to regulate consumer products that contain more than 0.1% weight MCCPs in the homogenous individual parts of products. Products containing less than this limit value may be sold legally.

1.2 Previous Process

A proposal to regulate MCCPs in consumer products was included in a previous proposal to regulate a number of hazardous substances in consumer products, which Norway submitted for national consultation and notified to the ESA (pursuant to Directive 98/34/EC) and the WTO in 2007. Norway received very few specific comments regarding the regulation of MCCPs. The bodies consulted requested that the Norwegian government agencies await the process taking place in the EU. This process has been in progress for several years now, and it is still not clear when it will be concluded.

The proposal now being notified is a revised version of the 2007 proposal and is a result of comments submitted during the consultation process carried out at the time.

2 Problem Description

2.1 Substance or Substance Group

This regulation proposal covers medium-chain chlorinated paraffins $C_{14\text{-}17}$ (MCCPs), CAS No 85535-85-9. MCCPs are better defined as a group of substances than a single substance. The relevant CAS number is the most commonly used for the group $C_{14\text{-}17}$, and is therefore the most specific one for MCCPs. There are several CAS numbers that are less specific and which include MCCPs, but which also cover either short-chain chlorinated paraffins (SPPCs) and/or long-chain chlorinated paraffins (LCCPs).

2.2 Definitions and Limitations

This draft regulation covers medium-chain chlorinated paraffins $C_{14\text{-}17}$ (MCCPs) used in consumer products.

Consumer products here refer to any and all products intended for consumers and that can reasonably be expected to be used by consumers, in line with the definition set out in section 2 a of the Norwegian Act of 11 June 1976 No 79 Relating to the Control of Products and Consumer Services (Norwegian Product Control Act). Applications already regulated in other rules and regulations were not evaluated with respect to alternatives and costs.

The regulation does not cover food products, food packaging, fertiliser, medical devices and means of transport, permanently mounted equipment for means of transport and tyres and similar accessories for means of transport. These applications will therefore not be described in greater detail in the environmental impact assessment.

2.3 Occurrence

MCCPs are synthetically produced and do not occur naturally in the environment. This means that all detections of MCCPs in the environment are a result of emissions from various sources, such as industry, products and waste.

The data show a significant occurrence of MCCPs in the Norwegian environment, both biological materials and sediments from freshwater and marine environment, among others, in Mjøsa, the biggest lake in Norway, which is an important source of drinking water. Detection of MCCPs in leachate from waste disposal sites and soil and sediment samples from disposal

sites show that products are a significant source of emissions of MCCPs into the environment. Additionally, MCCPs have also been detected in sediments in the Arctic, which indicates that it has the potential for long-range transport.

Monitoring data shows extensive dispersion into the environment in Norway of both short-chain (SCCPs) and medium-chain chlorinated paraffins (MCCPs), see *Fjeld et al., Norwegian Pollution Control Authority Report TA 2006/2004, 'Mapping select new organic priority substances – brominated flame retardants, chlorinated paraffins, bisphenol A and triclosan).'* The compounds have been detected in fish in both salt water and fresh water, from Drammen Fjord, Mjøsa and in Øyeren (Figure 2). In samples taken from the lake Øyeren, MCCPs was the dominant substance.

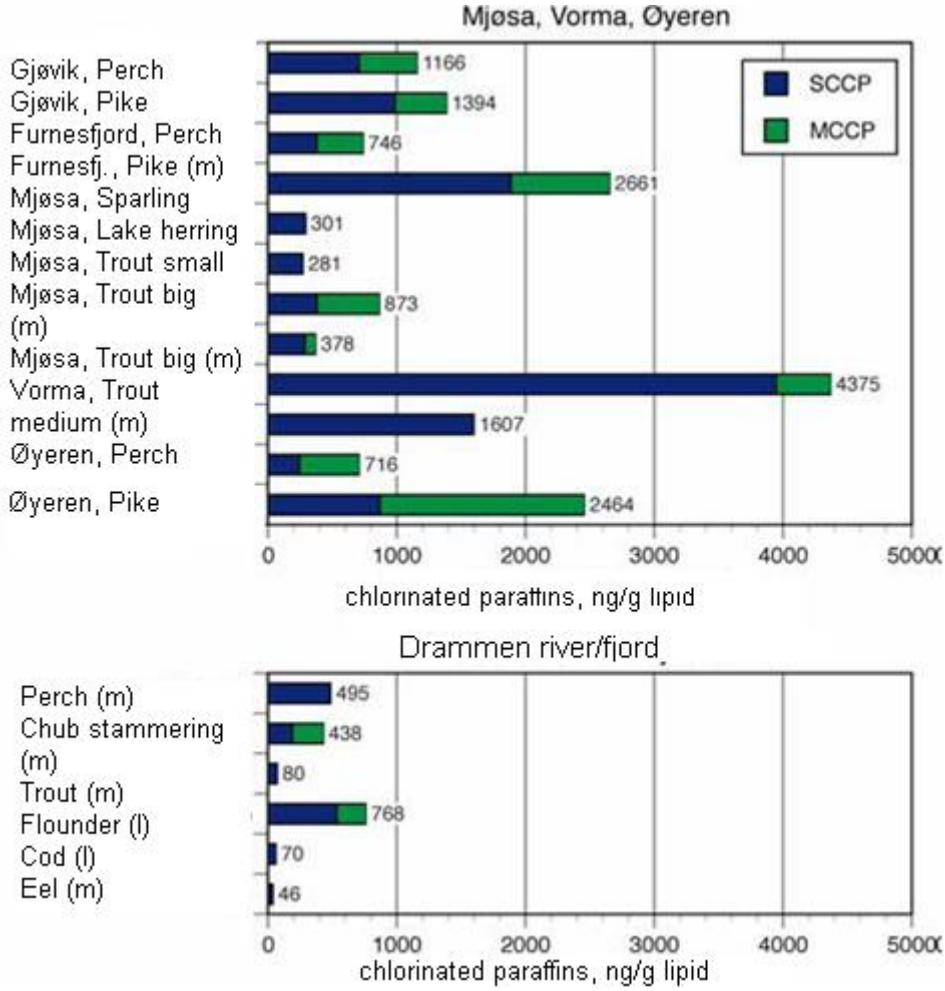

Figure 2: Concentrations of short-chain (SCCPs) and medium-chain chlorinated paraffins (MCCPs) in fish from Mjøsa, Losna and Øyeren (top panel) and from the outside estuary. Drammen River and inner Drammen Fjord (bottom panel). The concentrations (ng/g lipid) have been normalised against the contents of lipids in the samples. The samples consisted of composite samplings of whole homogenised fish, muscle fillets (m) or liver (l).

The substances were detected in all the sediment samples in the freshwater and marine environments in this study, among others, in sediments from Drammen River and Drammen Fjord, Outer Oslo Fjord, Trondheim and Tromsø Harbour and other marine stations along the coast (Figure 3). The substances were detected in fish and in sediments from Mjøsa. The

highest known level in Norway was observed in sediments taken from Drammen Fjord. At the bottom of Drammen River the ratio of SCCPs to MCCPs was 1:3. In fish, the highest levels (lipid normalised) were found in trout from the river Vorma.

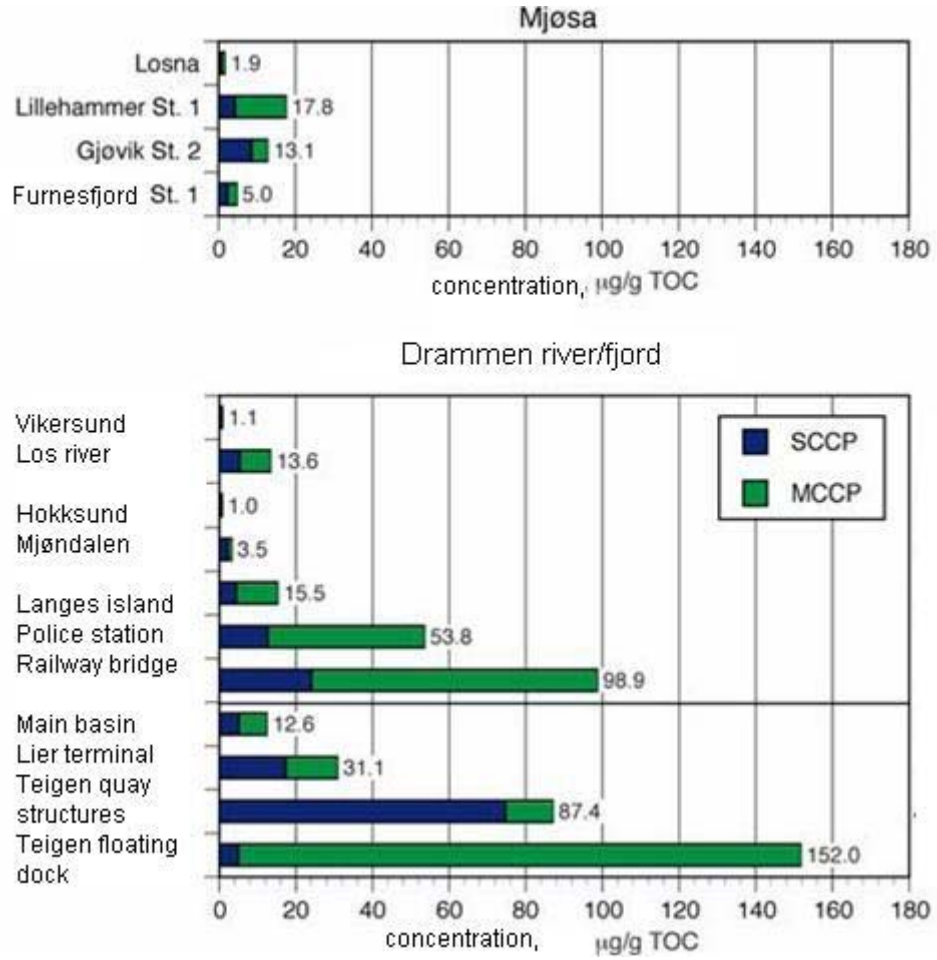

Figure 3: Concentrations of short-chain (SCCPs) and medium-chain chlorinated paraffins (MCCPs) in sediments from Losna and Mjøsa (top panel) and from Drammen River and the inner Drammen Fjord (bottom panel).
The concentrations (µg/g TOC) have been normalised against the contents of organic carbon in the samples.

Both short-chain and medium-chain chlorinated paraffins have been detected in leachate from waste deposit sites and in soil and sediment samples from deposit sites at levels ranging from 2,700 to 11,400 ng/g wet weight, *Schlabach et al. Norwegian Pollution Control Authority Report TA 1924/2002, 'Mapping brominated flame retardants and chlorinated paraffins.'* In these samples the presence of MCCPs tended to be greater than the presence of SCCPs. SCCPs are considered such a source of concern that they have been banned in Norway and in the EU. The properties of SCCPs and MCCPs have many similarities; it is only the length of the carbon chain that distinguishes them. In a major British study of river sediments sampled downstream from sewer treatment plans, concentration levels of SCCPs and MCCPs were found ranging from 200 to 63,000 ng/g dry weight. Taking into account loss on drying and differences between dry and wet weights, these findings correspond to the results from the Norwegian study. However, the samples from the Norwegian waste deposit sites were taken directly in the discharge and not in environmental samples near the discharge source.

There is a clear tendency for higher levels of MCCPs than SCCPs in sedimented materials from deposit site runoffs and in freshwater and marine sediments. SCCPs, however, dominate in samples taken from blue mussels and fish with the exception of fish from Øyeren. An explanation might be that bioconcentration (i.e. transition from water to biological materials) of SCCPs are greater compared to MCCPs. The MCCPs levels detected in the Norwegian environment are worrying, especially compared with the levels of SCCPs, which are banned.

The concentrations measured in dry weight from freshwater and marine sediments are on the same order and somewhat over the levels measured in industrially impacted German rivers: SCCPs from <5 to 700 ng/g dry weight (see *D. Muir et al.*, 2000). The concentrations of SCCPs and MCCPs in fish from Mjøsa are on the same order as the levels measures by Jansson *et al*. (1993) in freshwater fish from Storvindeln and Vättern: 6.6–30 ng/g wet weight or 570–1,000 ng/g lipid.

MCCPs have been detected in sediment sample in the Barents Sea, see *Bakke et al. Norwegian Pollution Control Authority Report TA-2400/2008, 'Mapping select organic contaminants in the Barents Sea 2007.'* The report indicates the potential for long-range transport seen in the light of similar studies in the Arctic. MCCPs have been detected but in relatively low concentrations in lakes without local sources of contamination in Southern Norway, *Fjeld et al., Norwegian Pollution Control Authority Report TA 2544/2009, 'Priority substances in freshwater fish 2008.'*

2.4 Health and Environmental Impact – Risk Assessment

Medium-chain chlorinated paraffins (MCCPs) are very likely to bioaccumulate. The Bioconcentration Factor (BCF) has been measured at up to 1,087 in fish. Data indicate that the BCF is greater in a few marine molluscs. There is MCCP data that cover the relatively long half-life in several species, monitoring data and accumulation via food.
An overall evaluation of this information indicates that for individual components in MCCPs, the total Bioaccumulation Factor (BAF)—which includes all uptake routes—is higher than the limit of 2,000 for bioaccumulation in the PBT criterion, *Annex XV Restriction Report Submitted by the United Kingdom, 30 November 2008.*

MCCPs are persistent. MCCPs have been detected in the food chain, in (among others) fish, cow's milk and breast milk. An EU risk assessment has demonstrated risks to organisms living in water and sediment (via dispersion of drainage water) and to soil organisms in terrestrial environments and birds, which are higher up in the food chain. Data might indicate that the potential for degradation decreases as the level of chlorination rises. That means that the compounds with a high degree of chlorination are more persistent than those with less chlorine. Some MCCP compounds in commercial products may have properties that can constitute a potential for long-range transport via the atmosphere.

The EU risk assessment (Risk Assessment Report, RAR August 2007) also concludes that there is a risk for kidney damage, cancer and risk to offspring through exposure (among others) via breast milk. MCCPs are classified in the 1st Adaptation to the new regulation on classification, labelling and packaging of substances and mixtures (1st Adaptation to Technical Progress (ATP) to Classification, Labelling and Packaging (CLP)). MCCPs are classified as "Very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment" (R50/53) and assigned with risk phrase "May cause harm to breast-fed

babies" (R64). MCCPs are classified with R64 and the potential for secondary poisoning therefore exists.

The EU risk assessment and the assessment of PBT properties (that is, persistency in the environment, bioaccumulation and toxicity) conclude that more data are required to determine if the substance satisfies the B criterion (bioaccumulation) on a purely technical basis. If we use the most reliable BCF value of 1,087 as the basis, MCCPs would not meet the B or the vB (very bioaccumulative) criteria, but it would meet the screening criterion for B. It has been decided to do further testing of bioaccumulation in fish, but the finding of the individual test in the proposed test program is deemed to be difficult to interpret (*Risk Assessment Report, RAR August 2007*). In the draft for the EU Risk Assessment Report of August 2007, it is emphasised that it might take a long time to obtain sufficient documentation to be able to draw certain conclusions and it is therefore recommended in the report that an assessment should be made to introduce regulations based on precautionary considerations. This reasoning is strengthened by the fact that, at least, some MCCP components possess PBT properties. There are indications that absorption of MCCPs via food is important, since higher values are found than what one should be able to expect from the BCF levels.

Measurements in the environment and biota can be critical for a conclusive assessment of the substance's potential for bioaccumulation and concentration in the food chain. It is emphasized in the draft for the Risk Assessment Report from August 2007 that MCCPs have lately been measured in the environment using certain methods and were detected in breast milk, cow's milk, some marine fish and marine mammals, even though the data—especially for fish and marine mammals—are still somewhat sparse. In November 2007 MCCPs were included in the action plan for the Baltic Sea on the basis of detected occurrences in the sediment and biota.

Short-chain chlorinated paraffins (SPPCs) are persistent and also meet the vP criterion (very persistent). It can therefore be assumed that MCCPs, too, meet the criteria for persistence. Annex XV Restriction Report submitted by United Kingdom, 30 November 2008 pointed out that there could be a need for considering additional measures with the arrival of the findings from the ongoing testing of MCCPs.

In summing up, the documentation shows that some MCCP components are persistent, bioaccumulate and are toxic, which means they have PBT properties. It is proposed that MCCPs should be classified as "Very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment" and assigned with risk phrase "May cause harm to breast-fed babies." MCCPs are measured in the environment and are detected in breast milk, cow's milk, some marine fish and marine mammals. Absorption of MCCPs via food is important, since higher values are found there than what one should expect from the bioconcentration levels.

MCCPs are a potential PBT substance, and acceptable concentration levels of such substances in the environment cannot be established with certainty. Regulating MCCPs cannot therefore only be based on the traditional risk assessment methods. Dispersion of substances that are persistent and are stored in living organisms constitutes a special problem because environmental accumulation is difficult to reverse and the long-term effects can be difficult to predict.

The key problem is the general dispersion of MCCPs into the environment from many different products throughout their entire lifecycle, through usage and as waste. This particularly applies to rubber and plastic products, including PVC where the emission can be significant. Because MCCPs are included in a lot of different products that gradually turn into waste, remaining quantities of waste will also be of significance to the dispersion of MCCPs into the environment. Since MCCPs in products do not react or are not converted during their service life, the entire quantity used in products may leak out into the environment through use or when the product ends up as waste. This problem becomes very relevant if concluding that MCCPs have PBT properties.

3 Range of Application

3.1 Identified Applications

Keyapplications:
MCCPs are included in a great many different products. The most known key applications are:

- Polyester (softener/flameretardant) (in Norway: in polyester for lifeboat production),
- Insulation and sealant compounds, glue,
- Paints, varnishes, surface treatment (primarily solvent-based),
- PVC (mainly wallpapers, floor coverings, cables, leisure and travel articles),
- Rubber cables,
- Lubricants/lubricating oils for metal processing,
- Leather impregnation, and
- Miscellaneous, such as rubber and non-carbon paper.

A few of these usage areas/products are only used commercially and will not be covered by the proposed regulation of MCCPs in consumer products. This applies, among other things, to:

- Lubricants for metal processing,
- Polyester for lifeboat production, and
- Floor coverings with special fire safety requirements.

3.2 Consumption and Potential for MCCP Emissions

Seventy-eight tonnes of MCCPs have been mapped out, which are registered in the Norwegian Product Register (PR) TA 2571/2010 ‘Priority hazardous substances - Status in 2007 and Discharge Prognoses.’ Imported articles are not included in these numbers. Table 1 illustrates the distribution of products across quantities and percentages. The key portion of the registered products consists of consumer products and such products have been marked with an asterisk.

Table 1:Distribution of MCCPs in products in Norway.

Category	**Sales in Norway 2007 (tonnes)**
Polyester (softener/flame retardant)	23 (approx. 30%)
Insulation and sealant compounds, glue*	46 (59%)
PVC*	Not registered in Product Register and in Norwegian manufactured PVC
Lubricants/oils	Approx. 3 (approx. 4%)
Paint and varnish products, surface treatment*	2 (2.5%)
Leather impregnation*	?
Other consumption, rubber, etc.*	Approx. 4 (5%)
Total	**78 tonnes**

* Includes consumer products in full or in part.

In 25 EU Member States (EU-25) in Western Europe, it is estimated that the sold quantity of MCCPs are 63,000 tonnes in 1997 and about 64,000 tonnes in 2006, *Annex XV Restriction Report Submitted by United Kingdom, 30 November 2008*. If we base our estimate on the assumption that Norwegian sales are equal to those in Western Europe and constitute about 1% of Western European sales (based on Norway's population's constituting about 1% of the population of EU-25), the approximate consumption is, respectively, about 630 tonnes in 1997 and about 640 tonnes in 2006. This is significantly higher than the registered quantities in Norway (78 tonnes), which is mainly a result of the extensive importing of articles, among others, various PVC products, which are not declared in the Norwegian Product Register. These quantities are therefore not included in the Norwegian figures. There is no registered use of MCCPs in Norwegian-manufactured PVC, but the substance has been found in a great many different imported soft PVC products, as illustrated in Table 2.

The figures from the EU are based on a different basis of calculation and cover a certain number of articles. The usage pattern in the EU distinguishes itself from that of Norway, because the numbers from the EU include the use of MCCPs in PVC for about 50% of the registered total quantities MCCPs. Calculations based on EU data suggest that there has barely been any reduction in consumption and emission of MCCPs for the period 1995–2007.

The Norwegian Climate and Pollution Agency has established the presence of MCCPs in many consumer products, especially soft plastic and rubber products such as wallpaper, electric wires and leisure articles such as backpacks, bags and camping chairs. MCCPs are used in a great many soft PVC products, especially where fire safety

is a critical factor, such as for cables and fireproof floor coverings. Analyses conducted by the Norwegian Climate and Pollution Agency of articles (mainly PVC) show large quantities of MCCPs in products where fire safety is not required, such as travel and leisure articles (sacks, bags, luggage, camping chairs, etc.) and building products, such as wallpaper (see Table 2). The analysed products contain MCCPs above the proposed limit value of 0.1% by weight and will therefore be included in the draft regulation. All these products are imported to Norway, and many of them are produced in low-cost countries in Asia. The use of MCCPs is inexpensive and production is simple, based partly on old technology.

Table 2: Analysis findings – presence of MCCPs in products (Norwegian Climate and Pollution Agency).

Product	**Detected quantities (ppm)**	**Content weight %***
Vinyl wallpaper	13,000	1.3
Wet room wallpaper	7,000	0.7
Camping chairs	16,300	1.63
Picnic bags	4,700	0.47
Backpacks	8,800	0.88
Backpacks	3,600	0.36
Belt bags	4,500	0.45
Expanding foam insulation (PUR)	125,000	12.5
Mittens	1,400	0.14
Rubber cables**	110,000	11.0
Electric cables**	26,000	2.6
Electric cables**	78,000	7.8

* Limit value in the proposed regulation is 0.1 percentage by weight.
** Will not be covered by the proposal if MCCPs are added as flame retardant.

The emission figures for MCCPs show that the main sources are products (see Figure 4). Emissions from other known sources are marginal.

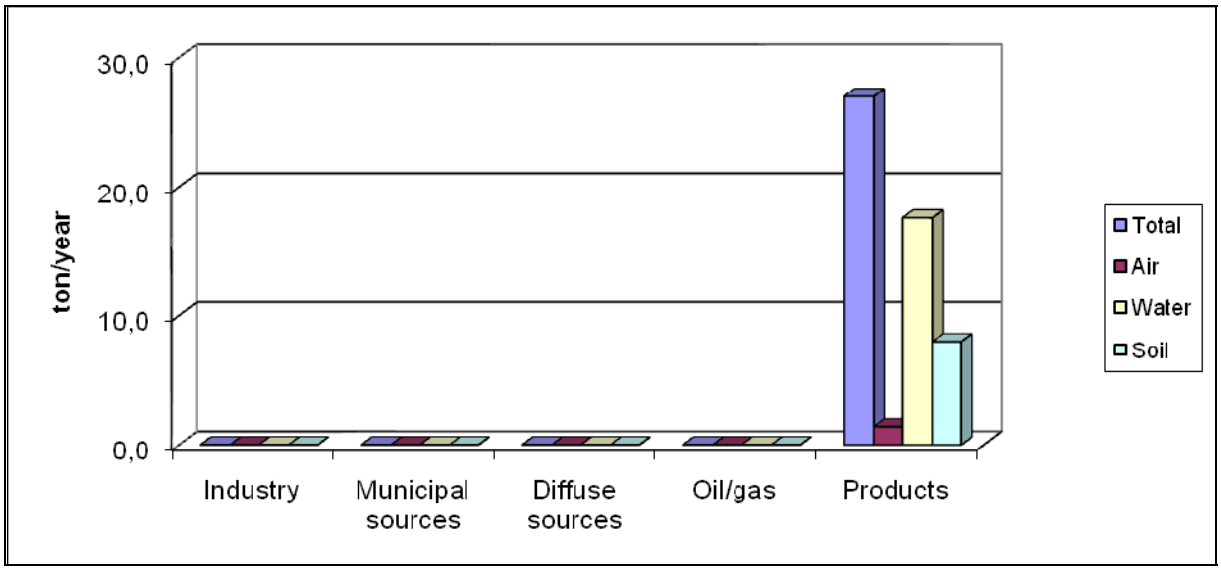

Figure 4: Various sources' contribution to national emission of MCCPs for air, water and soil as well as total emission of MCCPs in Norway (2007) – based on EU figures.

The key challenge is general dispersion of MCCPs into the environment from many different products throughout their entire lifecycle, through usage and as waste. This particularly applies to rubber and plastic products, including PVC where the discharge can be significant. Because MCCPs are included in a lot of different products that gradually turn into waste, remaining quantities of waste will also be of significance to the dispersion of MCCPs into the environment. Since MCCPs in products do not react or are converted during their service life, the entire quantity used in products may leak out into the environment through use or when the product ends up as waste (Annex XV Restriction Report submitted by United Kingdom, 30 November 2008).

According to EU's risk assessment, MCCPs in metal processing and leather impregnation can also result in significant emissions unless waste processing is optimal.

MCCP consumption and discharge/emission figures show that products constitute the largest usage area and the greatest potential for dispersion into the environment. Calculations based on EU data suggest that the estimate from the Norwegian Product Register is too low and that there has barely been any reduction in consumption and discharge for the period 1995–2007.

3.3 Alternatives

MCCPs are mainly used as a flame retardant and softening agent in PVC and rubber, such as leather processing and in paints, because of its physical properties. MCCPs are widely used because they are inexpensive and simple to produce. The alternatives have been described well in 'Environmental risk reduction strategy and analysis of advantages and drawbacks for medium chain chlorinated paraffins (MCCPs), Updated report, November 2008 – Entec report commissioned by the UK Department for Environment, Food and Rural Affairs (Defra), Annex XV Restriction Report Submitted by the United Kingdom, 30 November 2008 and RRS for MCCPs (February 2008) from Defra, United Kingdom.

Softener
Where MCCPs are only used as softener, there are several alternatives that both meet the technical properties and have less serious health and environmental properties. Phthalates—among others, DINP—can be used as a satisfactory alternative in PVC and is about 50% more expensive. The phthalate DEHP was previously used as a softener in PVC but is now hardly relevant because it has been listed as a Substance of Very High Concern (SVHC) (also called the "candidate list") under the EU regulatory framework Registration, Evaluation and Authorisation of Chemicals (REACH). It is also possible to use, among others, adipates, citrates and organophosphates. For rubber/polymers (with the exception of PVC), long-chain chlorinated paraffins (LCCPs) are among the alternatives. LCCPs have better health and environmental properties than MCCPs, but are more costly.

For many of the relevant PVC products where MCCPs are used as softening agent, there are alternative materials with elastic properties without the addition of softener. Several of these materials have better environmental properties than MCCPs. Alternative plastic materials are, among others, polyolefins, such as polyethylene (PE) and polypropylene (PP) and ethyl vinyl acetate (EVA).

Flame Retardant
There are alternatives to flame retardants, but not with the same selection as for softeners. They are more costly and several of the relevant alternatives also have environmental properties of concern, among others, trialkyl phosphate, which can be used in PVC. But there are also alternatives with acceptable risk to health and the environment. Aluminium trioxide in combination with antimony trioxide is used in cable sheathing. For some usages, phosphates are suggested as alternatives to MCCPs. Phosphates have poorer properties as softeners and therefore require greater quantities, which is something that results in higher costs.

MCCPs are used in soft PVC mainly and exclusively as a flame retardant. MCCPs are not registered in the production of PVC in Norwegian industry. We are not aware of any requirements relating to fire safety in PVC products for consumers. MCCPs are, among other things, used in floor coverings and wallpapers, but the Norwegian building codes (TEK), which implements the EU/EEA rules and regulations for constructing products (EU Construction Products Directive) , does not lay down such fire requirements for construction products. The building code only establishes framework requirements, and these may be met through other building technology solutions. MCCPs are used in, among other things, flameproof floor coverings and cables, but these are mainly for professional use where specifically required. The latter products will therefore likely not be covered by the proposal to regulate consumer products.

Leather Impregnation
There are several alternatives to MCCPs for leather processing, among others, LCCPs, phosphor compounds and various vegetables and animal oils. LCCPs have better health and environmental properties than MCCPs, and this presumably also applies to vegetable and animal oils. What is more uncertain is what health and environmental effects are linked to the phosphor compounds.

Paints
LCCPs are a good alternative to MCCPs for outdoor paints. The alternatives to various special paints are more uncertain. The latter products are primarily for professional use and are therefore not so relevant to consumers.

4 Current Policy

4.1 National Goals

The Norwegian Government has established the following national targets for eliminating and substantially reducing releases of priority hazardous substances by 2010 with a view of eliminating them by 2020, (see Prop. 1 S [2009-2010]). Proposition to the Parliament (Storting) for the 2010 budget year:

- Discharges or emissions of some priority hazardous substances (*cf.* Priority List) must cease or be reduced significantly by 2010.

- Discharges or emissions and use of chemicals that constitute a serious threat to health and the environment must be reduced continuously with the goal of ceasing emissions and discharges within one generation (i.e. by 2020).

Thirty substances and substance groups have been prioritised and placed on the Priority List, which covers this objective. The list was presented for the first time in Storting Report No 58 (1996-1997). Medium-chain chlorinated paraffins (MCCPs) are one of the substances included in the Priority List.

4.2 Existing Regulation

There is no existing, specific regulation for the use of MCCPs in consumer products nationally or within the EU. Short-chain chlorinated paraffins (SPPCs) are strictly regulated in Norway and in the EU. MCCPs are covered by the general Norwegian substitution requirement. This requirement has shown itself not to be sufficient.

4.3 Efforts in the EU

On behalf of the UK Department for Environment, Food and Rural Affairs (Defra), the consulting firm Entec prepared a draft for an updated environmental risk assessment (see MCCP Updated Stage 4 Report (Draft) February 2008), which was presented at the Risk Reduction Strategy (RRS) Meeting in the EU in April 2008. The report was subsequently updated in November 2008. It is concluded in the report that there is a need for combining several measures. There is no single measure that will limit the risk and also not result in significant downsides in relation to costs, technological efficiency and potential risk when using alternatives.

In the report the measures are summarized in two groups: (1) Measures based on measurable risks, and (2) Measures based on the precautionary principle. The updated version of the risk assessment concludes that measures must be evaluated based on “precautionary” principles because of MCCPs’ potential PBT properties and the impact of waste from products in the environment.

The EU has proposed a risk reduction strategy for MCCPs. That proposal suggests including MCCPs as a prioritized compound in Annex C of the Water Framework Directive (Directive 2000/60/EC, which is implemented in Annex 8 of the Norwegian Water Regulations. MCCPs are on the list of substances under consideration for inclusion in the Water Framework Directive in connection with the revision planned for completion in 2011. However, it is still uncertain if the substance will be included.
It is proposed that additional work with MCCPs be carried on under REACH. This will mean, among other things, that Safety Data Sheets (SDS) must be made available for downstream users from December 2010 as a result of MCCPs' being classified under the 1st Adaptation to the new regulation on classification, labelling and packaging of substances and mixtures (1st Adaptation to Technical Progress (ATP) to Classification, Labelling and Packaging (CLP).
The Risk Assessment Committee (RAC) has prepared an Annex XV Restriction Report Submitted by the United Kingdom, 30 November 2008, which was used as a case study for the membership countries' drafting of Annex XV documents. The time perspective for further regulation of MCCPs in EU is uncertain.

5 Proposal for Regulation and Reasons

The Norwegian Government received very few specific comments on its proposal to regulate MCCPs, as notified in 2007 (cf. section 1.2). A few bodies consulted requested that the Norwegian government agencies should await the process taking place in the EU. This includes testing for bioaccumulation of MCCPs in fish, in order to assess if MCCPs meet the criteria for PBT properties. The process has been going on for several years now and it is still not clear when the findings from the tests will be ready and the process concluded.
The Reporter for EU risk assessment and a few Member States propose that precautionary measures be evaluated. The EU has proposed that further work with MCCPs continue under REACH. The process in the EU will take time. Based on a precautionary assessment, it is therefore necessary to introduce national regulation pending future EU/EEA regulation concerning all relevant usage areas.

The proposal treats all consumer products equally. It covers both imported products and products produced in Norway.

5.1 Proposal for Regulation

It is proposed that consumer products containing MCCPs should be regulated in the following manner, and that this regulation should be included in the Regulation 1 June 2004 No 922 relating to restrictions on the manufacture, import, export, sale and the use of chemicals and other products hazardous to health and the environment (Product Regulation):

It is prohibited to produce, import, export and sell consumer products containing medium-chain chlorinated paraffins $C_{14\text{-}17}$ (MCCPs) (CAS No 85535-85-9) when the contents of the substance in the product's homogenous individual parts are higher or equal to 0.1% by weight.

The prohibition does not apply to products with special flame-retardant (fire-safety) requirements and where no satisfactory alternatives can be found.

The prohibitions in the first paragraph shall not apply to food products, food packaging, fertiliser, tobacco, medicine, means of transport, permanently mounted equipment for means of transport and tyres and similar accessories for means of transport. The prohibitions shall also not apply to spare parts for consumer products made available for sale before [XX MONTH YEAR – date of entry into force].

Consumer products shall here refer to any product intended for consumers or which can reasonably be expected to be used by consumers, cf. *the definition set out in section 2a of the Norwegian Act of 11 June 1976 No 79 Relating to Control of Products and Consumer Services (Norwegian Product Control Act). Homogenous individual parts shall here refer to a material that cannot be divided mechanically into various materials.*

For consumer products, this section shall take precedence to other provisions in this regulation.

6 Assessment of Other Measures

In Norway's assessment, the health and environmental effect that is sought with the proposal cannot be achieved with less restrictive measures. In the following, we evaluate alternative measures to our proposed regulation.

The proposal is motivated, among other things, by the consumer's lack of knowledge about health and environmental problems linked to the use of products, which may contain hazardous substances; how consumers need to protect themselves against potential exposure from these; how the products must be handled as waste. One might ask whether this is a problem that can be solved through information campaigns directed at consumers. However, based on OECD studies and other research, all experience shows that information campaigns are not sufficient to reduce emissions of priority hazardous substances. The measure is too diffuse and too uncertain to reach the necessary goals. Information campaigns are therefore not a relevant alternative to the proposed regulation.

From Norway's perspective, a corresponding health and environmental effect also cannot be achieved using economic measures, such as a tax. A tax is most appropriate in cases where the only aim is to reduce the use of the substance and in cases where there is no urgent need to reduce the emissions. In light of MCCPs' health and environmental hazardous properties, it is important that we have a reduction in use and emission that is as rapid as possible. This means that a tax is not an appropriate measure. Economic measures have generally turned out to be less effective than usage and sales restrictions to achieve reductions in emission. It would also be very difficult to establish a tax system that could produce the same effect as the proposed regulation. The large number of possible use areas would make it especially complicated to design and enforce a tax system.

It is also insufficient to introduce measures at a later stage in the sales chain. Collection schemes would, for example, be less restrictive on trade than a prohibition but would not lead to the same health and environmental impact. Regulation at the source of emission is the most effective regulation method when the objective is to achieve rapid reductions in emissions. If measures are introduced at some later stage, once the products have been put on the market, it is more difficult to introduce measures that effectively prevent uncontrolled dispersion of priority substances. Furthermore, the risk of leaks and emissions would be greater once the

reducing measures are introduced after the products have entered the market. It would be more effective to regulate near the source. Many consumers lack the relevant knowledge about collection schemes. It is difficult enough to monitor whether consumers are using already existing collection schemes.

Also, restrictions are a far more effective measure than labelling of products containing MCCPs. It is not likely that labelling in itself will reduce the risk of dispersing or exposure of MCCPs.

Voluntary agreements between the authorities and the industry have been effective measures in other environmental areas, among other things, in order to ensure proper waste handling. In this instance, where the purpose is to achieve a rapid reduction in emissions, voluntary agreements are, however, a far more uncertain measure than introduction of restrictions. Furthermore, MCCPs are present in a large number of imported products. These are difficult to capture with voluntary agreements. The proposed restrictions will therefore be a more effective measure to achieve the desired result.

7 Impact Assessment

7.1 Benefits

It is proposed that MCCPs should be regulated because the substance is a serious hazardous priority substance that has been detected in the environment and the food chain as well as in breast milk. MCCPs are assessed as a potential PBT substance. Documentation shows that some MCCP components have PBT properties and their presence in the environment and in breast milk constitutes a potential risk for humans and the environment.

MCCPs are used in Norwegian manufacturing (but not in the Norwegian PVC manufacturing industry) and in imported products. The use of MCCPs has increased in recent years, most likely as a result of the prohibition on PCB and SCCPs. There are alternatives to MCCPs that act as softening agents and are environmental, technically and financially acceptable. There are also products made out of different materials that meet the purpose.

The regulatory proposal has many positive, unquantifiable effects for health and the environment:

- The diffusion and entry of MCCPs into the environment from products ending up as waste will be reduced. The proposal will prevent MCCPs from leaking out into the environment when the product ends up as waste, either when it is being delivered for authorised waste processing or is otherwise leaked into the environment. The proposal, in the long term, will reduce the quantity of MCCPs from running off from deposit sites (in the form of leachate). The risk of diffuse dispersion of MCCPs will be reduced.
- The amount of MCCPs that can accumulate in the food chain will be reduced and it will be less likely that humans will ingest MCCPs through food and drinking water. This will result in a reduced risk of human health effects in the long term.
- The risk that MCCPs are introduced to children through breast milk will be reduced.
- Children will not be exposed to MCCPs when they suck on various products, such as mittens.

- Fish will, to a less degree, be harmed directly or indirectly through the uptake of MCCPs. Reduced emissions of MCCPs into the environment will contribute to reaching the goal of maintaining biodiversity.
- The potential for long-range transport of MCCPs will be reduced.
- Products containing more than 0.25% (2,500 ppm) MCCPs are defined as hazardous waste. The quantity of hazardous waste—and thereby also the costs related to delivery to authorised reception sites—will be reduced. Furthermore, demolition of buildings will be simplified and be less costly when it is no longer required to separate fractions containing MCCPs for hazardous waste delivery.
- The Norwegian Government's goal is to re-use and recycle the greatest possible number of waste fractions produced. For this to occur, these fractions must not contain hazardous priority substances. In doing so, the risk of health and environmental damages linked to products of recycled material will be reduced as will the use of new raw material resources. This proposal will contribute to ensure sufficient plastic material without MCCPs for material recovery.
- Positive effects for companies producing alternatives to MCCPs and those making products without MCCPs or alternative materials.

The regulatory proposal will produce significant reductions in the discharge of MCCPs. Broad regulation of the use of MCCPs in consumer products will be the best measure because there is a desire to significantly reduce the discharges in the short term.

7.2 Costs

Replacing MCCPs as softener with alternative substances will not result in a significant increase in costs. Estimates that have been performed (Environmental risk reduction strategy and analysis of advantages and drawbacks for medium chain chlorinated paraffins (MCCPs),' November 2008 – Updated Entec Report Commissioned by the UK Department for Environment, Food and Rural Affairs (Defra)) suggest an increase in raw material costs for phthalates of 3-4% for a few usage areas, such as wallpapers, and up to a 50% cost increase when MCCPs are replaced with DINP in, among other things, cables.

Replacing MCCPs with alternative flame retardant substances will result in increased costs—for example, in weatherproofing/sealing agents and soft PVC. However, there are other alternatives to PVC and alternative methods of weatherproofing (e.g. mineral wool). Exemptions are also proposed for products that have special fire safety requirements and where there are no satisfactory alternatives. This will result in a significant reduction in costs for the use of alternative flame retardants.

We propose that applications should be exempted where there are currently no acceptable alternatives. This applies to cases where there is a special need for MCCPs as a flame retardant and where there currently are no satisfactory alternatives.

It is difficult to obtain an overview of the total number of affected players. A limited number of players use MCCPs in their production in Norway. However, there are many importers who import products that may contain MCCPs. No MCCPs are produced in Norway, but MCCPs are used in the production of products/goods in Norway.

7.3 Summary and Conclusion

The proposed regulation may result in some increased costs but will result in a significant reduction in the introduction of MCCPs into the environment and will reduce the risk of health and environmental effects. In relation to the health and environment effects of MCCPs and the fact that there are satisfactory alternatives involving less risk to human health and the environment, we believe that the increased costs are acceptable. The proposal will have a positive effect for companies producing alternatives. Overall, our assessment is that the measure will not result in significant socioeconomic costs. We are anticipating that the benefits will outweigh the costs on the basis of the expected positive effects the proposal will have for health and the environment. The proposal makes exceptions for applications where there are no satisfactory alternatives.

The documentation shows that some MCCPs components possess PBT properties. Because MCCPs are a potential PBT substance, acceptable concentration levels of such substances in the environment cannot be established with certainty. The key challenge is the general dispersion of MCCPs into the environment from many different products throughout their entire lifecycle, through usage and as waste. This particularly applies to rubber and plastic products, including PVC where the discharge can be significant. MCCPs in products are not converted during the service life; the entire quantity used in products may leak out into the environment through use or when the product ends up as waste. Dispersion of substances that are persistent and are stored in living organisms constitutes a special problem because it is difficult to reverse accumulation in the environment, and the long-term effects can be difficult to predict. The precautionary principle therefore suggests that measures should be implemented.

Products are the most important and most significant range of application for MCCPs. It is not acceptable for such serious priority substances as MCCPs to be present in consumer products. Consumer products are an important source of uncontrolled dispersion of priority substances into the environment. It is therefore critically important that the use of products with such substances be limited. Consumer products are particularly important, since consumers lack the requisite knowledge about the health-related and environmental problems associated with their use and the waste disposal of these products. Consumers also do not have the requisite knowledge and ability to protect themselves against the emissions. The entire population, including vulnerable groups such as children, is therefore exposed to emissions from consumer products, either directly or indirectly via the environment.

The EU Commission has drafted a document about the application of the precautionary principle entitled ‘Communication from the Commission on the Precautionary Principle,’ (COM [2000] 1 Final). This document establishes that the precautionary principle mainly applies to future generations’ health and assessment of potential risk in a longer perspective.

From the Norwegian Government’s point of view, there is no secondary legislation (EU/EEA regulations or directives) preventing a national regulation of MCCPs in consumer products. Neither the rules set out in the EEA Agreement’s main part nor the case law of the EU Court are considered hindrances to the regulatory proposal. We refer here to what has been stated about the special health and environmentally hazardous properties of the substance as well as the special risk MCCPs constitute to health and the environment when they occur in consumer products. The proposed regulation is considered to be based on legitimate concerns (health and environmental concerns) and is considered an appropriate and necessary measure to reach the objective of reduced emissions of MCCPs from consumer products. The measure goes no

further than necessary to achieve the objectives we seek to achieve, *cf.* the impact assessment and previous statements relating to the proportionality of the measure.

8 References

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- EU Risk Assessment Report (RAR), August 2007.

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