

Appendix 1

Draft of new chapter concerning consumer products in the Norwegian Product Regulations:

Chap x. Hazardous substances in consumer products

I. Prohibition on certain hazardous substances in consumer products

Section x-1. Purpose

The purpose of this chapter is to limit the harmful effects on human health and the environment from consumer products, as well as to limit the content of hazardous substances in waste.

Section x-2. Scope

For consumer products, this chapter shall take precedence to other provisions in these regulations, unless indicated to the contrary in this chapter.

The chapter does not apply to food products, food packaging, fertilizers, medical equipment and tobacco, as well as means of transport, permanently mounted equipment for means of transport and tyres and similar accessories for means of transport.

Section x-3. Definitions

By the term *consumer product* is meant any product that is intended for consumers or that can reasonably be expected to be used by consumers, in line with the definition in section 2a of the Norwegian Act of 11 June 1976 No. 79 relating to the control of products and consumer services (the Product Control Act).

Section x-4. Prohibition on consumer products that contain certain hazardous substances

It is prohibited to produce, import, export or sell consumer products that contain substances in the table below when the content of the substance in the product's homogeneous component parts are greater or equal to the limiting values specified in the table.

Group of substances	Substance encompassed by the prohibition	CAS No.	Limit value (percent by weight)
brominated flame retardants	hexabromocyclododecane (HBCDD)	25637-99-4, 3194-55-6	0.1
	tetrabromobisphenol A (TBBPA)	79-94-7	1
chlorinated paraffins	medium-chained chlorinated paraffins, C14-C17 (MCCP)	85535-85-9	0.1
metals and metallic compounds	arsenic and arsenic compounds		0.01
	lead and lead compounds		0.01
	cadmium and cadmium compounds		0.01
organic tin compounds	tributyltin compounds (TBT)		0.001 in articles

	triphenyltin compounds (TPT)		0.001 in articles
fragrance substances	musk xylene	81-15-2	0.05
	musk ketone	81-14-1	0.05
perfluorinated compounds	Perfluorooctyl acid (PFOA) and individual salts and esters of PFOA	335-67-1, 3825-26-1, 335-95-5, 2395-00-8, 335-93-3, 335-66-0, 376-27-2, 3108-24-5	0.005 For textiles and other coated materials: 1 µg/m ²
surfactants	DTDMAC	68783-78-8	in total 0.1
	DODMAC/DSDMAC	107-64-2	
	DHTDMAC	61789-80-8	
other substances	Bisphenol A	80-05-7	freely available substance: 0.005 from [date], ¹ 0.0025 from [date] ²
	diethylhexylphtalate (DEHP)	117-81-7	0.1
	pentachlorophenol	87-86-5	0.1
	triclosan	3380-34-5	0.001

For metals, the prohibition in the first subsection does not apply to natural occurrences in coal, ore and ore concentrate.

II. Products and product groups that are not covered by the prohibition on certain hazardous substances in consumer products

Section x-5. Arsenic and arsenic compounds

The prohibition in section x-4 on products containing arsenic and arsenic compounds does not apply for:

- lead accumulators/sulphuric acid batteries,
- brass products,
- crystal and lead glass,
- ship-bottom paint and wood preservatives that are regulated in section 2-7 of these regulations.
- arsenic-treated timber that is regulated in section 3-6 of these regulations.

¹ When entry into force.

² Three years after entry into force.

- cosmetics and hygiene articles that are regulated in the Norwegian Cosmetics Regulations (26 October 1995)

Section x-6. Lead and lead compounds

The prohibition in section x-4 on products containing lead and lead compounds does not apply for:

- sailboat keels and ballast usages,
- glazings and enamels on products that must be presumed not to come into contact with food products,
- crystal and lead glass,
- lead diving belts,
- lead storage batteries,
- aviation fuels,
- paint that is regulated in section 2-5 of these regulations,
- ammunition, including shot pellet that is regulated in section 2-5 of these regulations,
- packaging, batteries and electrical and electronic products and equipment that are regulated in sections 3-11, 3-13 through 3-14 and 3-17 through 3-19 of these regulations,
- fuel that is regulated in section 3-16 of these regulations,
- cosmetics and hygiene articles that are regulated in the Norwegian Cosmetics Regulations (26 October 1995)

Section x-7. Cadmium and cadmium compounds

The prohibition in section x-4 on products containing cadmium and cadmium compounds does not apply for:

- electrical contacts for every application area that is surface-treated with cadmium or cadmium compounds in order to ensure the reliability required for the device in which they are installed,
- paints and lacquers with a high zinc content having a residual cadmium concentration of up to 0.1 percent by weight,
- use of cadmium in pigments, as a stabiliser in products and with the surface treatment of metal, provided its use is due to reasons of safety,
- galvanic anodes,
- cadmium in packaging, batteries and electrical and electronic products and equipment that are regulated in sections 3-11, 3-13 through 3-14 and 3-17 through 3-19 of these regulations.
- cosmetics and hygiene articles that are regulated in the Norwegian Cosmetics Regulations (26 October 1995)

Section x-8 Tributyltin and triphenyltin compounds

The prohibition in section x-4 on products containing tributyltin and triphenyltin compounds does not apply for application areas that are regulated in sections 2-8 of these regulations.

Section x-9. Musk xylene and musk ketone

The prohibition in section x-4 on products containing musk xylene and musk ketone does not apply for washing agents that are regulated in sections 3-10 of these regulations.

- cosmetics and hygiene articles that are regulated in the Norwegian Cosmetics Regulations (26 October 1995)

Section x-10. *The tensides DTDMAC, DODMAC/DSDMAC and DHTDMAC*

The prohibition in section x-4 on products containing the tensides DTDMAC, DODMAC/DSDMAC or DHTDMAC does not apply for washing agents that are regulated in sections 3-10 of these regulations.

Section x-11. Bisphenol A

The prohibition in section x-4 on products containing bisphenol A does not apply for:

- jointless floors,
- brake fluid,
- thermal paper
- plastic fillings for dental treatment
- cosmetics and hygiene articles that are regulated in the Norwegian Cosmetics Regulations (26 October 1995)

Section x-12. *DEHP*

The prohibition in section x-4 on products containing DEHP does not apply for:

- construction materials outdoor use
- toys and children's products that are regulated in section 3-12 of these regulations.
- cosmetics and hygiene articles that are regulated in the Norwegian Cosmetics Regulations (26 October 1995)

Section x-13. Pentachlorophenol

The prohibition in section x-4 on products containing pentachlorophenol does not apply for:

- textiles and leathers that are regulated in section 3-4 of these regulations.
- cosmetics and hygiene articles that are regulated in the Norwegian Cosmetics Regulations (26 October 1995)

Section §x-14. *Triclosan*

The prohibition in section x-4 on products containing triclosan does not apply for:

- Cosmetics and hygiene articles that are regulated in the Norwegian Cosmetics Regulations (26 October 1995)

Impact assessment of a proposal for prohibition on certain hazardous substances in consumer products

Impact assessment of a proposal for prohibition on certain hazardous substances in consumer products

The substances for which regulation is being proposed are high-priority hazardous substances and thus among the most dangerous substances we know of. Hazardous substances accumulate in the environment and in the food we eat. Hazardous substances represent a serious threat to the health of future generations, the environment and the future safety of food. It thus is extremely important to reduce emissions of them. Products are an important source of emissions. Consumer products are particularly important because the consumers lack the requisite knowledge concerning the problems relating to human health and the environment associated with the use and waste disposal of these substances. Nor do they have the requisite knowledge and equipment to be able to protect themselves from the emissions. The entire population, including vulnerable groups such as children, are thus liable to be exposed to emissions from the consumer products either directly or indirectly via the environment.

We therefore propose a prohibition on specified hazardous substances in consumer products when the content of the substance in the products' homogenous individual components is higher than or equal to the stipulated limiting value. These regulations do not apply to food, tobacco, food packaging, fertilizer and medical equipment, or means of transport, permanently installed equipment in means of transport, tyres and similar accessories for means of transport. These areas of use will therefore not be discussed further in the impact assessment. To the extent that the substances are utilised as biocides and/or pesticides, it is the regulations in the Norwegian Biocide Regulations and the Norwegian Regulations relating to Herbicides that apply. For example, arsenic, pentachlorophenol, tributyltin and triphenyltin compounds were banned as biocides from 1 September 2006. Furthermore, some exemptions are proposed from the prohibition for areas of use where we believe it will not be possible to introduce a ban in the short-term, either because there are no alternatives, these alternatives would be very costly, or the substance is already regulated by harmonised EEA regulations. Furthermore, to begin with, exemptions from the prohibition will be granted to some substances that are regulated by the Norwegian Cosmetics Regulations. Cosmetics are regulated by the Norwegian Cosmetics Regulations on the basis of health considerations alone. The environmental protection authorities will, at a later date, assess whether or not there is a need and opportunity for even stricter regulation of certain substances in cosmetics on the basis of environmental considerations.

For most of these substances, we expect that the costs associated with a prohibition would be relatively low. This includes arsenic, diethylhexylphtalate (DEHP), medium-chained chlorinated paraffins (MCCP), the musk compounds, perfluorooctyl acid (PFOA), some selected surfactants, triclosan, pentachlorophenol, tributyltin and triphenyltin compounds (TBT/TPT), tetrabromobisphenol A (TBBPA) and hexabromocyclododecane (HBCDD). The combination of the low costs and the serious effects of the emissions lead us to expect that the benefits associated with the proposed regulation of these substances in consumer products will be greater than the costs. For the other substances, bisphenol A, lead and cadmium, the prohibition could entail costs; however we expect that such would not be significant. Information about the quantities of emissions, their distribution in the environment and possible harmful effects to health and environment, is however uncertain, and we do not have precise estimates for the impacts. Thus we are not able to say with a large degree of certainty that the benefit would be greater than the costs.

As the report shows, the effects of these types of substances are quite serious in that they are persistent, bioaccumulating and/or toxic, e.g. toxic to reproduction. Based on these circumstances the effects have to be regarded as irreversible. Monitoring data from Norway in particular data from recent screening studies, shows widespread contamination of the substances in the environment. To acquire conclusive knowledge of the long-term effects of these substances would require a very long time. Therefore, and viewed on the basis of the serious consequences, a delay is not deemed to be a relevant solution. Hence in our perception a prohibition should be implemented as quickly as possible on the basis of the existing information for all the substances being proposed.

Scope of the prohibition

The following substances are included in this simplified impact assessment on the basis of summaries that have been prepared for each of them:

- Arsenic
- Bisphenol A
- Lead
- Diethylhexylphtalate (DEHP)
- Cadmium
- Medium-chained chlorinated paraffins (MCCP)
- Musk compounds (Muskxylene and muskstone)
- PFOA and related compounds
- Triclosan
- Selected surfactants (DTDMAC, DODMAC/DSDMAC, DHTDMAC)
- Pentachlorophenol (PCP)
- Tributyltin and triphenyltin compounds (TBT and TPT)
- Hexabromocyclododecane (HBCDD)
- Tetrabromobisphenol-A (TBBPA)

Description of the environmental risks

The substances concerned are hazardous substances. Hazardous substances are substances that represent a particularly large problem to human health and the environment. These substances:

- are not very degradable and accumulate in living organisms and have serious long-term effects on human health or are extremely toxic in the environment
- are very persistent and very bioaccumulating in living organisms
- are being found in the food chain in levels that give rise to concerns, or

give rise to equivalent reason for concern, i.e. endocrine disrupters or heavy metals

Hazardous substances in consumer products are distributed via many different types of products. This does not comprise professional use and the consumers often do not have adequate knowledge of the safe use of the products, access to protective equipment or knowledge of the safe disposal of discarded products. This involves exposure for the users, either directly or indirectly via the environment, e.g. because of emissions to the environment during service life or because the residual products to a large extent end up in normal household waste. Monitoring data confirm that hazardous substances that are deposited in landfills will gradually leak out. Because they are persistent and do accumulate in living organisms, a long time can elapse before the damage is detected. At that point in time it would be impossible or very difficult and expensive to avert or repair the damage that this

damage will have to be regarded as irreversible. It thus is important to place a special focus on consumer products now.

Current policies

Due to these extremely unfortunate characteristics with respect to human health and the environment, we have a goal in Norway of significantly reducing the emissions of hazardous substances in the short run and of eliminate use and emissions completely before 2020, the so called one generation target, as described in Report to the Storting No. 14 (2006-2007) entitled "Together for a Non-toxic Environment – Preconditions for a Safer Future". The hazardous substances being proposed for the prohibition are all given a high priority in this report. The proposed hazardous substances are all substances that fulfil the criteria for the one generation target. As a first step on the road to achieving the generation target in 2020, a goal has previously been set of halting or significantly reducing emissions of prioritised hazardous substances by no later than 2010. The list of prioritised hazardous substances is often referred to as the government's priority list. The Norwegian Pollution Control Authority produces an annual report on national emissions of prioritised hazardous substances, the so-called priority list report. The contributions of products to emissions of hazardous substances has in recent years increased in comparison with the traditional sources of emissions such as industry, where the emissions have been reduced to a substantial degree in recent years. A reduction in emissions from products is thus essential in order to achieve Norway's goals in the area.

It is important to protect consumers from consumer products that have a direct impact on their health. However, it is also important to regulate products where consumers are important contributors to the impact and distribution of prioritised hazardous substances into the environment. The use of consumer products results in the extensive and fairly uncontrollable distribution and exposure of many prioritised hazardous substances into the environment. Many consumer products currently end up as hazardous waste. By regulating these products it will also be possible to reduce the quantity of the hazardous waste generated by consumer products.

Assessment of measures

It is important that a significant reduction in the emissions occur quickly. This concerns a broad spectrum of quite different undesirable products distributed across a large area, which it is important to stop before they appear on the market. We are thus of the opinion that a general prohibition on the use of the specified hazardous substances in consumer products would be the best measure. The use of financial measures would be less relevant because the aim is to reduce the emissions significantly in the short run. A complete system for charges intended to include many different substances in many different products, both as chemicals as well as imported articles containing hazardous substances, would be extremely complicated to design and especially to enforce.

Basis for the assessments

The proposal for a prohibition on selected hazardous substances in consumer products includes the assessment of many substances with many different application areas. Acquiring information concerning the content of substances in the very substantial number of products that are on the market in Norway is quite complicated. The Norwegian Product Register contains information on chemical substances and products (preparations). This register contains, however, no information on the content of substances in articles. In addition, estimating the quantities of emissions from these products, their distribution in the environment and ascertaining precisely which human health and environmental damages would arise in consequence of such emissions is extremely complicated. We do not have valuation estimates for these damages for most of these substances. There have been limited

opportunities to acquire new and supplementary background documentation. We have primarily based the assessments on what is available in existing reports regarding application areas, the quantities being used and the consequences.

As far as the regulations in the EEA Agreement and the WTO regulations are concerned, this measure is regarded as appropriate and justified given the chemical substances' specific properties that are hazardous to health and the environment when they occur in consumer products. Nor in our opinion are there any specific legal regulations/total harmonisation requirements in the EEA chemicals regulations that hinder the proposed regulations. We have assessed the regulations in the EEA Agreement for each individual substance and proposed exemptions from the prohibition in those cases where we believe the individual substance's area of use is regulated via the totally harmonised EEA regulations.

Estimated costs

The assessments of the consequences associated with the proposed prohibition are extremely overarching and primarily a description of application areas and characteristics concerning human health and the environment, as well as possible alternatives. As regards the costs for the industries associated with a possible prohibition, we do know that for most of the application areas there are alternative products on the market without hazardous substances. We are not familiar with the details of all of these alternatives and are not in possession of cost estimates for such. In the cases where we know that commercially available alternatives do exist, we have as an very rough estimate presumed that a prohibition would not involve costs of any significance.

We endeavour to point out that the proposed prohibition is based upon limiting values. This means that it is allowable for the products to contain small quantities of the substances concerned. The magnitude of the quantity allowed varies from substance to substance. This modification has been made in order to simplify the implementation and thus reduce the costs to industry. For many application areas we have proposed that exceptions should be made to the prohibition. This is primarily due to strict regulation of some applications pursuant to the EEA-treaty, the lack of real alternatives, a diminished effect on human health and the environment of including the application area or a prohibition in the application area being expected to involve significant costs. In the formulation of the prohibition, an emphasis has thus been placed on reducing the costs as much as possible without great impact on the environmental efficiency of the proposal to too large of an extent. We are thus of the perception that the benefits of the measure can be expected to be greater than its costs.

The importance of taking a precautionary approach

There is a large degree of uncertainty associated with a number of aspects of the proposed prohibition. We are however of the perception that the measure, on the basis of the precautionary principle, ought to be implemented even though we do not have fully adequate information regarding the substances concerned and the costs that the prohibition would involve for the players. In the Norwegian Government Agency for Financial Management's guide for the treatment of uncertainty in economic analyses, four criteria are established for when the precautionary principle can be used. These are:

1. Large and non-quantifiable uncertainty associated with future consequences
2. The damages can be dramatic
3. The damages will be irreversible
4. There is no time to wait and see how things develop and to acquire more information

For all the substances, the uncertainty is large and it is impossible to quantify, among other things, the harmful effects to human health and the environment with the present state of our

knowledge. Experience indicates that extremely unfavourable effects often gradually come to light with these types of substances. Hence there are good reasons to believe that such will also be the case with these substances. As is brought to light in the foregoing, the effects of these substances are quite serious in that they are not very degradable and are bioaccumulating. These are conditions that in practice must necessarily be regarded as being irreversible. To acquire sufficiently certain knowledge of the long-term effects of these substances would take an extremely long time. When viewed against the background of the dramatic consequences these have, we do not deem that to be a relevant solution. The substances concerned thus in our perception fulfil all these criteria and the prohibition hence ought to be implemented in our perception as soon as possible on the basis of the existing information.

Further work – acquisition of further information

We are of the opinion that we are familiar with the majority and the most important of the application areas for all the substances. Among other things, we have extensive contacts with the industrial sector and have arranged two open meetings for the sector during the course of the work in order to check out our proposal with them. We cannot, regardless, completely ignore the possibility that there could be special application areas that we have no knowledge of. This could also be due to the importers not knowing that their products contain the substances concerned. We expect that industry will, in connection with this request for comments, go through the application areas for the individual substances even more thoroughly. If there then, or even in some other context, should be information presented concerning new application areas or other important information, we will carry out a new assessment in conjunction with the relevant industrial sector.

Assessment of impact associated with the regulation of hazardous substances in consumer products. Arsenic

1) Substance or group of substances

Arsenic and arsenic compounds

2) Known application areas

Metallic arsenic:

- Brass

Chemical arsenic compounds:

- Glass goods (window glass, crystal, lead glass)
- Glass beads for road markings (not a consumer product)
- Plastic/PVC products (including garden articles, travel/leisure time articles, construction materials and wallpapers)
- Lead accumulators
- Grout
- Textiles
- Earlier in pesticides, wood preservatives included
- Ship-bottom paint
- Cosmetics
- Mineral fertiliser

Arsenic was previously used in lead shot, pesticides and wood preservatives. The use of lead shot is now banned in Norway. Arsenic can occur in imported products, especially products based on recycled materials such as glass and plastic. It also appears as impurities in other products, particularly those containing lead.

The list does also contain application areas and products that are only for occupational use and they will not be covered by the prohibition on certain hazardous substances in consumer products.

3) Description of human health and environmental risks

Arsenic and arsenic compounds: Persistent and toxic for many organisms even in small concentrations. Very toxic for aquatic organisms, may cause long-term effects in the aquatic environment. Some compounds are carcinogenic. This substance fulfil all the criteria for use of the precautionary principle mentioned in the introduction.

The emissions of arsenic have been reduced by approx. 8 % from 1995 up through the present. They are expected to diminish further, in part due to the ban already imposed on CCA-impregnated woodwork and lead shot. Long-range transport of arsenic has decreased significantly. Arsenic has been found in the air, reindeer, sediments and soil. Emissions from products are responsible for fully 91 % of the total emissions, which comprised approx. 28 tons in 2004. Of the product emissions, emissions from the CCA-impregnated woodwork currently in use comprised fully 23.6 t, and emissions from lead shot approx. 2.6 t. The arsenic in the CCA-impregnated woodwork currently in use is substantial, and will contribute to emissions for a long time into the future. These emissions will not be affected by a prohibition on the use of arsenic in products.

4) Occupational use

- Wood preservation with CCA
- Glass beads for road markings
- Mineral fertilizer

Application areas only for occupational use will not be covered further in this overview.

5) Existing regulation of arsenic in consumer products

Only regulations that deal with the products within the scope of the proposed prohibition are mentioned here.

- Cosmetics: the Norwegian Cosmetics Regulations, appendix IIA: Banned. Trace quantities permitted: in cosmetics 5 mg/kg, in toothpaste 0.5 mg/kg (laid down by the Ministry of Health and Care Services (formerly the Ministry of Health and Social Affairs))
- Ship-bottom paint and impregnated wood: Norwegian Product Regulations, Sections 2-7 and 3-6 regulating arsenic and arsenic compounds in ship-bottom paint and impregnated wood (laid down by the Ministry of the Environment).

6) Alternatives

By replacing materials containing lead (for example lead in plastic and glass), arsenic, will also disappear since it also occurs as an impurity in these materials, will also disappear. In Europe a production method is used in which arsenic cannot be utilised for technical reasons (float glass). In China a production method is used in which arsenic is used in the process (machine glass). There are commercially available alternatives that do not contain arsenic and lead.

7) Proposal for additional regulation

The regulations that already exist for arsenic and its compounds in the Product regulations, will be kept as it is. The existing regulations of arsenic in ship-bottom paint and wood preservation do not have a limit value for the content of arsenic, and it is not desirable to make the existing ban less stringent.

Arsenic and arsenic compounds in cosmetics and food packaging are regulated in specific regulations that are based exclusively on health considerations. To begin with, exemptions will be made from the extensive prohibition on hazardous substances in consumer products containing arsenic that are regulated in the Norwegian Cosmetics Regulations. The environmental protection authorities will, at a later date, assess whether or not there is a need and opportunity for even stricter regulation of arsenic in cosmetics on the basis of environmental considerations.

As far as the regulations in the EEA Agreement and the WTO's regulations are concerned, the ban against arsenic in consumer products is regarded as appropriate and justified given the substance's specific properties that are hazardous to health and the environment combined with the specific risk the substance constitutes when it occurs in consumer products. In our opinion the health and environmental goals we are seeking to achieve justify the disadvantages regulation results in for the players, and other means are considered inappropriate.

In our opinion there are no specific legal regulations/total harmonisation requirements in the EEA chemicals regulations for arsenic that hinder the proposed regulation.

It is proposed that arsenic and arsenic compounds should be further regulated because arsenic

is on the priority list and it is already regulated for use as biocide, e.g. fouling agent and wood preservative. Arsenic is found in the environment. An expanded ban would involve a reduced incidence in the environment, as well as it will reduce the risk to human health.

We are proposing a prohibition on consumer products with more than 0.01 percent arsenic by weight in the product's homogeneous component parts.

Examples of known application areas for arsenic that will be prohibited are plastic/PVC products (including garden furniture, travel/leisure time articles, construction materials, window glass and wallpapers, grout and textiles. The list is not exhaustive; all areas of use within its scope that do not fall under the exemptions will also be covered by the ban. It is proposed that the regulations listed under point 5 be maintained as they are and they will not be changed by this ban. It is proposed to exempt a few further products from the ban in the short-term, either because there are no alternatives or because these alternatives would be very costly.

The following application areas are proposed exempted from the prohibition:

- lead accumulators
- brass products
- crystal glass
- lead glass

Socio-economic assessment

The emissions of arsenic have been reduced significantly in recent years, and today comprise approx. 1 ton from products. The proposal for regulating arsenic will contribute to reducing this significantly. The content of arsenic in products is in most cases due to the lead content of the products. Products without arsenic and arsenic compounds do exist. Regulation of the lead content of the same products is also being proposed, so the proposed regulation of arsenic is thus not expected to involve extra expenses. The benefits are hence expected to be greater than the costs.

An extensive prohibition on the use of arsenic in consumer products would be the best means because one wants to reduce emissions significantly in the short-term, cf. the national target.

Assessment of impact associated with the regulation of hazardous substances in consumer products. Bisphenol A

1) Substance or group of substances

Bisphenol A, CAS. No. 80-05-7

2) Known application areas

- Polycarbonate plastic (in packaging for food products and other items, electronic devices, medical equipment, means of transport, CD disks, greenhouse walls, building materials, returnable bottles, baby bottles, protective helmets)
- Plastic fillings for dental treatment
- PVC (as a hardener, catalyst, binding agents, stabiliser for example for floor coverings, building plastic, garden hoses, baby bottles, toys, travel articles)
- Epoxy resin production (many different epoxy resins, including jointless floors, EE products, coatings on boxes and paper, building structures, coating powder)
- Paint, lacquer, glue (binding agents, hardeners)
- Thermal paper
- Polyol for the production of polyurethane
- Production of tetrabrombisphenol-A (TBBPA, flame retardant) (can be degraded to bisphenol A under certain environmental conditions)
- Brake fluid, automobile tyres

The list also contains application areas/products that are only for occupational use and they will not be covered by the prohibition on Bisphenol A in consumer products.

Quantity of the substance being used

2003 max. 71.5 tons. Declared to the Norwegian Product Register (PR) on 6 March 2006. (declaration in PR obligatory).

Distributed by product types:

- Binding agents for paint, glue, etc.: 3.7 tons
- Jointless floors (for example epoxy floors): 1.4 tons
- Other hardeners, hydraulic fluids: 11.3 tons
- [Hardeners for paint, lacquer, etc.: 9.4 tons](#)
- Other stabilisers: 1.4 tons
- Other: 18.2 tons.

Total net quantity (i.e. produced + imported - exported): max. 46.6 tons.

Max. total quantity (produced + imported + exported) in the time period spanning 2000-2004 has varied between 71.5 tons and 34 tons.

In addition, there are also many different solid products, particularly polycarbonate and other plastics (PVC) and painted products that contain bisphenol A. Analyses accomplished by the Norwegian Pollution Control Authority show a range in products from 2800 mg/kg to 2 mg/kg, with approx. half of them being under 10 mg/kg. The highest residual monomer content in polycarbonate that was analysed was 50 mg/kg, typical residual monomers were < 10 mg/kg.

Number of players in Norway/large or small

- Many players, especially importers. In all probability a limited number of manufacturers.

Norwegian production/import/export

- No longer in Norwegian-produced PVC, but is used in, among other things, Norwegian-produced paint. Found in many imported products.

3) Description of human health and environmental risks

Bisphenol A appears to be readily biodegradable, and is not considered to be bioaccumulating (LogKow 3.4, BCF 67). Bisphenol A is classified as an irritant and skin sensitizer and as toxic to reproduction (Rep. Cat 3, R62 possible risk of impaired fertility). Endocrine disrupting effects have been shown (estrogenic effects). Bisphenol A is harmful to aquatic organisms and a classification with R52 harmful to aquatic organisms) has been proposed for bisphenol A in the EU in the 30.ATP; due to endocrine disrupting effects. New studies have been done concerning effects at very low doses in fish, and studies on snails are underway. The substance is included in the OSPAR (Oslo and Paris Convention) list of substances of possible concern, but not on the list for priority action. An EU risk assessment for the substance is available.

Monitoring data shows widespread occurrence in the environment in Norway; (the Norwegian Pollution Control Authority report 2004, Annex 1). Bisphenol A has been found in sludge and sediments (silt) from Lake Mjøsa, the Drammen River, inner Drammen Fjord and in sediments along the Norwegian coast. Bisphenol A has also been found in fish in the same areas. Bisphenol A was found in several freshwater fish species, the highest concentrations was found in trout in the river Vormå. In the vicinity of individual large population centres along the coast, somewhat elevated levels have been found in marine sediments. It was also found in blue mussels and cod liver along the coast. In general, low levels were found in marine areas, both in sediments and in biological samples. The brominated flame retardant TBBPA may be another possible source for bisphenol A in the environment.

Conclusion: The substance fulfils the criteria for the generation target (based on toxicity to reproduction and endocrine disrupting effects and the fact that it is widely found in the environment and biota in Norway).

This substance fulfils all the criteria for the precautionary principle mentioned in the introduction.

Bisphenol A can be released to the environment from the production process, and with the use of the substance in the production of a number of plastic raw materials - i.e. epoxy resins, polycarbonates, PVC and phenol plastic resins. The most important sources of exposure are thermal paper and the PVC industry. The substance has endocrine disrupting effects both in fish as well as in snails. The primary source of terrestrial exposure is the spreading of sludge from sewage treatment systems. There is a need for measures to reduce the risks with respect to the environment for a number of application areas. As regards the consumers there is no direct exposure, but polycarbonates and epoxy resins that contain bisphenol A are incorporated into many consumer products. A Norwegian survey shows very large variation in different products on the markets varying from less than 10 mg/kg free available residuals to about 2500 mg/kg (The report is only in Norwegian, can be made available on request). Potential exposure to the consumers may occur if free monomers are made available or if the

polymer is damaged or degraded, for example in epoxy resin-based paint, wood fillers and glue. Emissions to the environment from products during service life or waste may cause indirect exposure of humans.

4) Occupational use

- Polycarbonate plastic in medical electronic equipment (regulated by the Norwegian Medicines Agency)
- Production of tetrabromobisphenol-A
- Polyol for production of polyurethane

Application areas only for occupational use will not be covered further in this overview.

5) Existing regulation of bisphenol A in consumer products

Only regulations that deal with the products within the scope of the proposed prohibition are mentioned here.

Cosmetics: the Norwegian Cosmetics Regulations, appendix IIB: Banned, laid down by the Ministry of Health and Care Services (formerly the Ministry of Health and Social Affairs).

6) Alternatives

The Norwegian Pollution Control Authority knows that there are also commercially available PVC products without bisphenol A.

7) Proposal for additional regulation

There is no existing regulation of Bisphenol A in the Norwegian Product Regulations. The use of bisphenol A in cosmetics is regulated by specific regulations on the basis of health considerations. Regulation exists for the use of bisphenol A with a limit for migration in materials that come into contact with food products. Most of the products in this category satisfy these limits with a good margin. San Francisco has implemented a prohibition on bisphenol A in products for children under three years of age.

It is proposed that bisphenol A should be regulated because the substance fulfils the criteria for the generation target. Bisphenol A is found in the environment.

It is proposed that the content of bisphenol A in consumer products should be regulated with two-stepped limits; a prohibition on more than 0.005 percent free bisphenol A by weight in homogeneous component parts upon entry into force and a prohibition on more than 0.0025 percent by weight beginning three years after entry into force.

Examples of known areas of use that will be covered by the regulations are polycarbonate plastics, epoxy resin products, paint, varnish, glue and PVC. The list is not exhaustive; all the areas of use within its scope that do not fall under the exemptions will be covered by the ban. The use of bisphenol A in cosmetics is already banned pursuant to the Norwegian Cosmetics Regulations and it is therefore proposed exempted from this ban. Exemptions from this ban are also proposed for some other products in the short-term, either because there are no alternatives or because these alternatives would be very costly.

The following application areas are proposed exempted from the prohibition:

- Brake fluid
- Thermal paper
- Joint-less floors
- Plastic fillings for dental treatment

As far as the regulations in the EEA Agreement and the WTO's regulations are concerned, the ban against bisphenol A in consumer products is regarded as appropriate and justified given the substance's specific properties that are hazardous to health and the environment combined with the specific risk the substance constitutes when it occurs in consumer products. In our opinion the health and environmental goals we are seeking to achieve justify the disadvantages regulation results in for the players, and other means are considered inappropriate.

In our opinion there are no specific legal regulations/total harmonisation requirements in the EEA chemicals regulations for bisphenol A that hinder the proposed regulation.

Socio-economic assessment

The proposal will contribute to reducing hazards to human health and the environment associated with that part of the bisphenol A that is most easily accessible in the products. The costs of this regulation are thereby reduced in relation to a prohibition based upon the total content of bisphenol A in the products.

In overall terms, it is assumed that the proposal would not involve significant socio-economic costs. An extensive prohibition on the use of bisphenol A in consumer products would be the best means because one wants to reduce emissions significantly in the short-term.

Assessment of impact associated with the regulation of hazardous substances in consumer products. Lead

1) Substance or group of substances

Lead and lead compounds

2) Known application areas

Metallic lead:

- Lead accumulators/sulphuric acid batteries
- Construction materials (roofing, etc.)
- Sailboat keels and other ballast uses in boats
- Lead belts for diving
- Cable caps
- Alloys (incl. soldering alloys)
- Fishing gear (for commercial and recreational activities)
- Ammunition
- Weights (balancing automobile tyres, curtain weights, etc.)
- Electrical equipment, light sources
- Other (including lead glass windows)
- Lead used as shielding from radiation

Chemical lead compounds:

- Glass (picture tubes, light sources, crystal)
- Stabiliser (especially in imported PVC plastic products including such things as construction materials like profiles for doors and windows, wallpaper, floor covering, gutters, pipes, contacts, cables, toys, travel articles, plastic boxes, leisure time articles)
- Pigments (in paint and lacquer)
- Pigments (in plastic)
- Glazings/enamel
- Glue/binding agents
- Blast sand
- Lubricants
- Laboratory chemicals (precipitants, process aids, accelerants)
- Print colours
- Packaging
- Other (aviation fuel, automobile tyres, brake linings)

The list also contains application areas and products that are only for occupational use and they will not be covered by the prohibition on hazardous substances in consumer products.

Quantities registered in Norway in 2004 (arrow up/down: Trend in consumption from 2003)
(Ref. Prioritised hazardous substances. Status 2004):

Metallic lead:

- Metallic products (workshop and construction) 4332 t ↑
- Fishing gear 260 t ↑
- Other met. products 226 t

Chemical lead compounds:

- Paint, lacquer, etc. 14 t ↑
- Stabiliser in PVC 21 t ↑
- Glazings 2,4 t ↓
- Other (glue, binding agents, precipitants, process aids, print colours, accelerants, lubricants) 22 t ↑

Norwegian production/import/export:

Use of lead as a stabiliser in Norwegian production of PVC plastic has been reduced. Lead can occur in imported products, particularly products of PVC plastic and products of recycled plastic.

3) Description of human health and environmental risks

Lead bio accumulates and is persistent. Toxic in low concentrations, has both acute and chronic effects on human health and the environment. Acutely toxic to humans. Chronic lead poisoning can have neurotoxic and immunological effects. Can cause damage to the haematogenic system. Lead is toxic to reproduction, can cause brain damage, foetus injuries, fertility impairment and haematogenesis in humans. Children are more at risk than adults. Accumulates in the skeleton and soft tissue. Very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment.

Lead has been found in soil, sediments in lakes and fjords, species of animals.

This substance fulfils all the criteria for the precautionary principle mentioned in the introduction.

Long-range transport of lead is approx. 8 times greater than the national emissions to air, however the long-range transport is less than the total Norwegian emissions to the air and water. Metallic lead comprises a smaller pollution problem than lead compounds. This is because for most of the application areas for metallic lead, the emissions associated with its use will be minimal. If the products are given satisfactory treatment as waste, they will not comprise any significant problem. The use of metallic lead that will comprise a problem is associated with products that are difficult to collect after their use. This typically applies for fishing gear, curtain weights and ammunition.

The emissions of lead have been reduced by approx. 24% from 1995 up through the present. They are expected to decline further, including due to lead shot being banned and the phasing out of lead in ammunition in the Norwegian Armed Forces. We have limited information concerning the content of lead in imported products. Analyses performed by the Norwegian Pollution Control Authority in 2005 and 2006 show findings of lead in different imported plastic products. Increased import of products, particularly PVC products from countries without regulations in the area, will comprise a more significant source of lead emissions in the Norwegian market as we gradually gain control over more of the most significant sources at present.

Emissions from products comprise approx. 96% of the total emissions in Norway. In 2004 this comprised a total of 437 tons. The emissions are due essentially to lead shot and other ammunition (366 tons), fishing gear (65 tons), aviation fuel (private aeroplanes), automobile tyres, brake linings, PVC plastic, light bulbs, blast sand and pigments and corrosion protection in paint. There are also possible emissions from glue, binding agents, print colours,

lubricants and laboratory chemicals.

Other large application areas such as batteries/accumulators, building materials, cables, soldering tin, X-ray protection, sailboat keels, glass items and glazings involve extremely small emissions.

4) Occupational use

- Lead in products that can come into contact with food
- X-ray protection
- Blast sand
- Lubricants
- Laboratory chemicals
- Print colours
- Lead in components in vehicles
- Paint
- Fertilizers

Application areas only for occupational use will not be covered further in this overview.

5) Existing regulation of lead in consumer products

Only regulations that deal with the products within the scope of the proposed prohibition are mentioned here.

- Cosmetics: the Norwegian Cosmetics Regulations, appendix IIA: Banned. Trace quantities permitted: In cosmetics 20 mg/kg, In toothpaste 1 mg/kg (laid down by the Ministry of Health and Care Services (formerly the Ministry of Health and Social Affairs))
- EE (electrical and electronic) products: Limit of 0.1%. Exceptions for fluorescent lamps and misc. alloys. RoHS [Restriction of Hazardous Substances Directive]/Norwegian Product Regulations section 3-18, appendix V (laid down by the Ministry of the Environment)
- Paint: Prohibition on lead carbonates and lead sulphates. Exceptions can be given for restoration work. Dir 89/677/EEC art. 17 and 18. Norwegian Product Regulations section 7-1 (decision) (laid down by the Ministry of the Environment)
- Packaging: The sum of lead, cadmium, mercury and hexavalent chromium must not exceed 100 mg/kg. Exceptions for packaging solely produced from lead crystal glass. Dir 94/62/EC art 11/Norwegian Product Regulations section 3-11 (laid down by the Ministry of the Environment)
- Batteries: Prohibition on inbuilt batteries with over 0.4% lead (with exceptions in appendix II to chap. 3 in the Norwegian Product Regulations). Dir 91/157/EEC, Dir 93/86/EEC and Dir 98/101/EC. Norwegian Product Regulations section 3-14 b, cf. 3-13 d. (laid down by the Ministry of the Environment) (A new EU battery directive is recently laid down)
- Petrol: Prohibition on lead quantities over 0.005 g/l. Dir 98/70 and Dir 03/17. Norwegian Product Regulations section 3-16, appendix IV (laid down by the Ministry of the Environment) The limit has been set because some lead occurs naturally in crude oil. Lead is not added to petrol in Norway or in the EU.
- Lead shots: Prohibition on lead shots. Norwegian Product Regulations section 2-5 (laid down by the Ministry of the Environment)

6) Alternatives

Denmark has its own regulations that regulate the use of lead and lead compounds for selected application areas. A consequence of this is that we know that satisfactory alternatives exist for the following application areas:

- Construction materials: Aluminium and rubber polymer (www.catsub.dk)
- Thread type solder: Lead-free thread type solder (www.catsub.dk)
- Stabiliser in PVC: Stabiliser based on calcium zinc
- Paint: Alternatives to paint containing lead exist (www.catsub.dk)
- Fishing gear: other metals such as for example steel and iron

Alternative commercial products exist without lead and they fulfil the requisite technical requirements for the product, also for most of the other application areas.

7) Proposal for additional regulation

It is proposed that the regulations that already exist for lead and lead compounds in the Norwegian Product Regulations be kept as they are. Some bans/regulations set no limiting values for the content of lead, and some regulations have been harmonised with the EEA regulations. There is no desire to soften existing bans.

Lead and lead compounds in cosmetics are regulated by specific regulations that are based exclusively on health considerations. To begin with, exemptions will be made from the extensive prohibition on hazardous substances in consumer products containing lead that are regulated in the Norwegian Cosmetics Regulations. The environmental protection authorities will, at a later date, assess whether or not there is a need and an opportunity for even stricter regulation of lead in cosmetics on the basis of environmental considerations.

As far as the regulations in the EEA Agreement and the WTO's regulations are concerned, the ban against lead in consumer products is regarded as appropriate and justified given the substance's specific properties that are hazardous to health and the environment combined with the specific risk the substance constitutes when it occurs in consumer products. In our opinion the health and environmental goals we are seeking to achieve justify the disadvantages regulation results in for the players, and other means are considered inappropriate.

In our opinion there are no specific legal regulations/total harmonisation requirements in the EEA chemicals regulations for lead that hinder the proposed regulation.

It is proposed that lead and lead compounds should be further regulated because lead is on the priority list. Lead is found in the environment. At present lead is banned in paint (lead carbonates and lead sulphates), as well as in shot. An expanded ban would reduce the incidence in the environment, as well as reduce the risk to human health.

Denmark already has a prohibition on lead and lead compounds. The proposal being submitted is in line with the ban in Denmark.

A prohibition is proposed on consumer products with more than 0.01 percent lead by weight in the product's homogeneous component parts.

The following examples of known application areas and products containing lead will be prohibited: Construction materials, stabiliser in PVC, pigments in plastic, paint and lacquer,

fishing gear, use as weights, glue and binding agents. The list is not exhaustive. Unknown areas of use will also be covered by the ban. It is proposed that the regulations listed under point 5 be maintained as they are and they will not be changed by this ban. It is proposed to exempt a few further products from the ban in the short-term either because there are no alternatives or because the alternatives would be very costly.

The following application areas are proposed exempted from the prohibition:

- Sailboat keels and other ballast uses in boats
- Lead belts for diving
- Glazing and enamels on products that must be presumed to not come into contact with food products
- Crystal
- Lead glass
- Lead accumulators/sulphuric acid batteries
- Aviation fuel
- Ammunition (except for lead shot which is already prohibited)

For most of the application areas, commercially available alternative products exist in the Norwegian and Danish markets.

Socio-economic assessment

The proposed regulations will reduce the remaining quantity of lead emissions from products by approx. 50%. This will involve reduced emissions to water, and reduce future costs associated with waste disposal. At the same time, somewhat increased costs must be expected during the transition to alternatives, especially other stabilisers in PVC.

An extensive prohibition on the use of lead in consumer products would be the best means because one wants to reduce emissions significantly in the short-term, cf. the national target. In overall terms, we do not therefore anticipate that the measure will involve socio-economic costs of significance.

Assessment of impact associated with the regulation of hazardous substances in consumer products. Diethylhexylphtalate (DEHP)

1) Substance or group of substances

Diethylhexylphtalate (DEHP), CAS No. 117-81-7

2) Known application areas

- Softeners for plastic/PVC (for example travel effects, medical equipment, toys, garden articles, construction materials for indoor and outdoor use, rainwear, misc. plastic articles, wrapping materials)
- Softeners for rubber
- Softeners for paint, glue

DEHP is not produced in Norway. Norwegian manufacturers of PVC have replaced DEHP with other types of softeners, among others DINP. DEHP occurs as a softener in imported plastic products. The use of DEHP in products is estimated to be approx. 150 tons in 2004. Softeners in toys are regulated separately.

The national emissions of DEHP are uncertain. A rough assessment indicates that the emissions have been reduced significantly since 1995. Emissions from products (DEHP) are roughly estimated to be approx. 2.4 tons in 2003 (80%). The emissions from existing products must be expected to continue for many years into the future even if the proposed prohibition enters into force.

The list also contains application areas and products that are only for occupational use and they will not be covered by the prohibition on use in consumer products.

3) Description of human health and environmental risks

DEHP degrades relatively easily in water, but more slowly in sediment and soil. Moreover the degradation rates are highly temperature-dependent and degradation under Nordic climate conditions is expected to be slow. DEHP shows a high potential for bioaccumulation in aquatic invertebrates for example crustaceans (BCF 2500 for mussels), but bioaccumulation in fish is more moderate. DEHP is absorbed easily through the intestines and air passages. Animal studies indicate that the lungs, liver, kidneys and testicles are target organs and that fertility and development are adversely affected. DEHP may have endocrine disrupting effects, possibly due to an anti-androgenic effect. DEHP is classified as toxic to reproduction with R 60/63 (may impair fertility, possible risk of harm to the unborn child). DEHP can be transferred via breast milk.

Has been found in freshwater, saltwater, waste water, air, organisms, sediments and sludge, in indoor air and food products such as meat, fish and milk. DEHP has also been found in breast milk.

DEHP is a priority substance under the EU Water Framework Directive.

This substance fulfils all the criteria for the precautionary principle mentioned in the introduction.

4) Occupational use

Softeners in plastic for medical equipment.

Application areas only for occupational use will not be covered further in this overview.

5) Existing regulation of DEHP in consumer products

Only regulations that deal with the products within the scope of the proposed prohibition are mentioned here.

- Cosmetics: the Norwegian Cosmetics Regulations, appendix IIA: Banned, (laid down by the Ministry of Health and Care Services (formerly the Ministry of Health and Social Affairs))
- Phthalates (including DEHP) are in general regulated in toys and products for children. The regulation follows from harmonised EEA regulations, and is implemented in section 3-12 of the Norwegian Product Regulations, (laid down by the Ministry of the Environment).

6) Alternatives

Alternatives to DEHP are other types of phthalate compounds and other types of softeners.

7) Proposal for additional regulation

The prohibition on phthalates in toys, etc. is connected to whether the substance has been added. Since the proposed prohibition relates to a limiting value, and not to whether the substance has been added, the existing provision ought to regulate these products. Medical equipment must be exempted from the prohibition.

A prohibition is proposed on consumer products with more than 0.1 percent DEHP by weight in the product's homogeneous component parts.

The following examples of known application areas and products containing DEHP will be prohibited: plastic/PVC rubber, paint and glue. The list is not exhaustive; all areas of use within its scope that do not fall under the exemptions will also be covered by the ban. It is proposed that the regulations listed under point 5 be maintained as they are and they will not be changed by this ban. It is proposed to exempt a few further products from the ban in the short-term, either because there are no alternatives or because these alternatives would be very costly.

The following application areas are proposed exempted from the prohibition:

- construction materials for outdoor use

As far as the regulations in the EEA Agreement and the WTO's regulations are concerned, the prohibition against DEHP in consumer products is regarded as appropriate and justified given the substance's specific properties that are hazardous to health and the environment combined with the specific risk the substance constitutes when it occurs in consumer products. In our opinion the health and environmental goals we are seeking to achieve justify the disadvantages regulation results in for the players, and other means are considered inappropriate.

In our opinion there are no specific legal regulations/total harmonisation requirements in the EEA chemicals regulations for DEHP that hinder the proposed regulation.

Socio-economic assessment

Further regulation of DEHP is proposed because DEHP is on the priority list and is already regulated in Norway and the EU with limits on its content in products for children less than 14 years of age. DEHP has been found in the environment and can involve serious damage to human health.

DEHP is an undesirable alternative to medium chained chlorinated paraffins (MCCP) (as a softener). Other conceivable softeners exist that are satisfactory alternatives, both for DEHP and for MCCP.

Products without DEHP exist. The Norwegian plastics industry no longer uses DEHP, however the substance can occur in imported products. Expanded regulation would reduce emissions by approx. 20% in relation to the quantities recorded in the Norwegian Product Register. In addition to this, there are also emissions from imported products that are not registered. The products for which regulation is being proposed have the greatest significance in terms of reducing risk to human health. An extensive prohibition on the use of DEHP in consumer products would be the best means because one wants to reduce emissions significantly in the short-term, cf. the national target.

Replacement of DEHP as a softener with alternative substances will not involve increased costs of any significance. There are reasons to expect that the benefits are greater than the costs.

Assessment of impact associated with the regulation of hazardous substances in consumer products. Cadmium

1) Substance or group of substances

Cadmium (Cd) and cadmium compounds

2) Known application areas

- Surface treatment of metal/cadmium plating
- Pigments in plastic (incl. EE products)
- Stabiliser in PVC (major imported PVC products such as leisure time articles, wallpaper, children's toys)
- Paint and lacquer
- Textiles
- Batteries and accumulators
- Galvanic anodes
- Fertilizer
- Packaging
- Tobacco
- Drain cleaning agents

Registered quantities in Norway in 2003 (cadmium content in imported products has not been examined. Ref. Prioritised hazardous substances. Status 2003 and emission prognoses

(Analysis of measures)):

Cadmium plated prod. 0

Stabiliser in PVC 0

Drain cleaning agents 0.01 t

Paint and lacquer (ship painting, biocide) 4.87 t

There are significant contributions of cadmium from long-range transport. The long-range transport is approx. twice as large as the total Norwegian emissions of cadmium. Emissions of cadmium from Norwegian industry have been reduced significantly since 1995. During the period from 1995 – 2003 the national emissions were reduced by a magnitude of 70%. There is little to indicate that the cadmium emissions will be reduced significantly up to 2010. Emissions from products comprise approx. 18% of the total national emissions. This corresponds to approx. 0.3 tons. The most substantial part of the emissions from products comes from galvanic anodes and fertiliser. In recent years there have been increased imports of products, particularly plastic products, from countries that do not regulate the area. This could lead to an increased amount of cadmium in the Norwegian market.

The list mentioned above also contains application areas/products that are only for occupational use and they will not be covered by the prohibition on use in consumer products.

3) Description of human health and environmental risks

Cadmium is acutely and chronically toxic for humans and animals. Cadmium is extremely acutely toxic for aquatic organisms, especially in freshwater, and acutely toxic for mammals. Cadmium compounds have chronically toxic effects in many organisms, even in very small concentrations. Most cadmium compounds are carcinogenic. Cadmium is bioaccumulating in fish and mammals, and has a long biological half-life in mammals. Small quantities of cadmium can damage the liver, lungs, kidneys and skeleton. Cadmium has been found in vegetation, surface soils and in animals, fjords and watercourses.

This substance fulfils all the criteria for the precautionary principle mentioned in the introduction.

4) Occupational use

- PVC packaging in medical equipment: European pharmacopeia: < 0.6 ppm (Regulated by the Norwegian Medicines Agency)
- Pigments
- Stabilisers
- Surface treatment

These application areas only for occupational use will not be covered further in this overview.

5) Existing regulation of cadmium in consumer products

Only regulations that deal with the products within the scope of the proposed ban are mentioned here.

- Cosmetics: the Norwegian Cosmetics Regulations, appendix IIA: Banned. Trace quantities permitted: In cosmetics 5 mg/kg, in toothpaste 0.1 mg/kg (laid down by the Ministry of Health and Care Services (formerly the Ministry of Health and Social Affairs))
- Pigments: Prohibition on "placing in the market", but limit 0.1 percent by weight if high zinc content. In addition prohibition on use for colouring associated with a number of listed substances/mixtures of substances. Dir 91/338/EEA. Norwegian Product Regulations section 2-11 (laid down by the Ministry of the Environment)
- Stabiliser: Banned in a number of listed products. For import, export and sales, the ban applies for over 0.01%. Dir 91/338/EEA. Norwegian Product Regulations section 2-12 (laid down by the Ministry of the Environment)
- Surface treatment of metal: Banned for a number of listed sectors/application areas. Exception for electrical contacts. Dir 91/338/EEA. Norwegian Product Regulations section 2-13 (laid down by the Ministry of the Environment)
- Batteries and accumulators: Certain bans on cadmium in batteries and accumulators. Norwegian Product Regulations sections 3-13 and 3-14 (laid down by the Ministry of the Environment)
- EE products: Norwegian Product Regulations sections 3-17 through 3-19 (laid down by the Ministry of the Environment)
- Packaging: The sum of lead, cadmium, mercury and hexavalent chromium must not exceed 100 mg/kg. Exceptions for packaging solely produced from lead crystal glass. Dir 94/62/EC art 11/Norwegian Product Regulations section 3-11 (laid down by the Ministry of the Environment).

6) Alternatives

Products without cadmium and cadmium compounds exist for most of the application areas. The major part of the PVC that is produced in Europe is without cadmium.

7) Proposal for additional regulation

The regulations that already exist for cadmium and cadmium compounds in the Norwegian Product Regulations shall be kept as they are since these are in line with the harmonised EEA regulations.

Cadmium and cadmium compounds in cosmetics and food packaging are regulated in specific regulations that are based exclusively on health considerations. To begin with, exemptions will be made from the extensive prohibition on hazardous substances in consumer products containing cadmium that are regulated in the Norwegian Cosmetics Regulations. The environmental protection authorities will, at a later date, assess whether or not there is a need and opportunity for even stricter regulation of cadmium in cosmetics on the basis of environmental considerations.

It is possible to prohibit the substance in consumer products, with the exceptions that follow explicitly from the directives mentioned above. General exceptions due to reasons of safety must be maintained (pigment, stabiliser, surfacetreatment).

As far as the regulations in the EEA Agreement and the WTO's regulations are concerned, the prohibition on cadmium in consumer products is regarded as appropriate and justified given the substance's specific properties that are hazardous to health and the environment combined with the specific risk the substance constitutes when it occurs in consumer products. In our opinion the health and environmental goals we are seeking to achieve justify the disadvantages regulation results in for the players, and other means are considered inappropriate.

In our opinion there are no specific legal regulations/total harmonisation requirements in the EEA chemicals regulations for cadmium that hinder the proposed regulation.

It is proposed that cadmium and cadmium compounds should be further regulated because cadmium is on the priority list and is already highly regulated in Norway and the EU with limitations on it as a stabiliser and pigment in different types of plastic, PVC product groups and in paint. Cadmium is found in the environment. An expanded ban would reduce the incidence in the environment, as well as reduce the risk to human health.

A prohibition is proposed on consumer products with more than 0.01 percent cadmium by weight in the product's homogeneous component parts.

The following examples of known application areas and products containing cadmium will be banned: Surface-treated metal/cadmium plating, pigments in plastic, stabiliser in PVC, paint and lacquer, textiles and drain cleaning agents. The list is not exhaustive. Unknown areas of use will also be covered by the ban. It is proposed that the regulations listed under point 5 be maintained as they are and they will not be changed by this ban. It is proposed to exempt a few further products from the ban in the short-term either because there are no alternatives or because the alternatives would be very costly.

The following consumer products will be exempted:

- Galvanic anodes,
- Paint and lacquer with high zinc content
- Electrical contacts

Socio-economic assessment

The use of cadmium is already strictly regulated in Norway, however the formulation of the regulations are over-complex and leave room for loopholes, particularly for imported products. It is difficult to check whether products comply with the requirements of the existing regulations. The primary purpose of expanded regulation is to fill gaps in the existing regulations, as well as to simplify the enforcement of the regulations. The substance occurs primarily in imported products from, among other places, Asia. With respect to the Norwegian plastics industry, it is possible to produce PVC without cadmium. Most of the manufacturers have already found alternatives to cadmium in products, and the costs of an expanded ban would thus not be significant. In overall terms, An extensive prohibition on the use of cadmium in consumer products would be the best means because one wants to reduce emissions significantly in the short-term, cf. the national target. The measure would not involve socio-economic costs of significance.

Assessment of impact associated with the regulation of hazardous substances in consumer products. Medium-chained chlorinated paraffins (MCCP)

1) Substance or group of substances

Medium-chained chlorinated paraffins C14-C17 (MCCP), CAS. No. 85535-85-9

Is the most frequently used CAS No. for this group (most specific for MCCP). Various CAS numbers exist that are more non-specific and include MCCP, but which in addition either include short-chained or long-chained chlorinated paraffins.

2) Known application areas

Main application areas:

- Polyester (softener/fire retardant) (in Norway: In polyester for lifeboat production)
- Insulation and sealants, glue
- Paint, lacquer, surface treatment (primarily solvent-based)
- PVC (in the EU – primarily wallpapers, floor coverings, cables, leisure time and travel articles)
- Lubricants/lubrication oils for metalworking
- Leather preservation
- Other, including rubber

The list also contains application areas and products that are only for occupational use and they will not be covered by the prohibition on use in consumer products.

Quantities and distribution of MCCP:

A material flow analysis from 2005 estimates 54-64 tons of MCCP in chemicals/products registered in the Norwegian Product Register. Imported in articles have not been surveyed. The table below shows the distribution in the Norwegian data collection efforts (quantities and percentages) and the distribution percentages in all types of products in the EU. The Norwegian data collection efforts give a biased picture however of the use of MCCP in PVC because there are extensive imports of different PVC products that are not declared in the Norwegian Product Register. Analyses of imported articles show large quantities of MCCP in cables, construction materials such as wallpapers and travel and leisure time articles (sacks, bags, suitcases, camping chairs, etc.).

Category	Turnover in Norway 2005 tons	Distribution of use in EU 2003
Polyester (Softener/fire retardant)	15 – 20 (31%)	6.5%
Insulation/sealants/glue *	30 – 35 (55%)	* jointly 15%
Paint and lacquer products, surface treatment *	1	
PVC	not recorded in Norwegian produced PVC	60%
Lubricants/oils	approx. 5 (8%)	15%
Leather preservation	?	2.5%
Other uses, including rubber	approx. 3 (5%)	

In total	54-64	
<p>Consumption in Norway of MCCP has increased from 1996 to 2003 (imported articles not included), among other reasons due to a prohibition on SCCP. Use in Norwegian-produced PVC is not registered. In the EU, the use of MCCP in PVC has been reduced, while the other application areas, including sealants and joint fillers, are increasing.</p> <p><i>Number of players in Norway/large or small</i> We have only a very minor overview of the number of players. However there is only a limited number who use MCCP in their production. In contrast, there are many importers who import products that can contain MCCP.</p> <p><i>Norwegian production/import/export (Ref.: Norwegian Product Register)</i> MCCP is not produced in Norway. In contrast, MCCP is used in the production of products in Norway. We have no overview of any possible export of these products. Approx. 20 t is used in the Norwegian polyester industry as a fire retardant in the production of lifeboats (not a consumer product). Approx. 30 t is used for insulation/sealant materials and glue. Approx. 10 t is used for cutting fluids for special production/products (not a consumer product).</p>		
<p>3) Description of human health and environmental risks Medium-chained chlorinated paraffins have a high potential for bioaccumulation (Bio concentration factors up to 1087 has been measured in fish). Medium-chained chlorinated paraffins are persistent. Medium-chained chlorinated paraffins have been found in the food chain, including in fish, in cow milk and in breast milk.</p> <p>MCCP is proposed to be classified as very toxic to aquatic organisms and they can cause long-term adverse effects in the environment. In addition, it is proposed to be classified with the risk phrase "May cause harm to breast-fed babies."</p> <p>This substance fulfils all the criteria for the precautionary principle mentioned in the introduction.</p> <p>Monitoring data shows widespread occurrence in the environment in Norway of both short-chained (SCCP) and medium-chained chlorinated paraffins (MCCP) (The Norwegian Pollution Control Authority, Annex 1). They have been found in blue mussels and cod liver along the Norwegian coast from inner Oslo Fjord to Varanger Fjord. Furthermore, they have been found in fish from Drammen Fjord, Lake Mjøsa and in Lake Øyeren. The substances have also been found in sediment from the Drammen River and Drammen Fjord, as well as Outer Oslo Fjord and the harbours at Trondheim and Tromsø, plus other marine stations along the coast. Furthermore, the substances have been found in fish and sediment from Lake Mjøsa.</p> <p>The highest level recorded in Norway was observed in sediment from Drammen Fjord. In sediments, the medium-chained chlorinated paraffins dominate, but in fish the short-chained chlorinated paraffins are dominating. Medium-chained are also found in fish and in the Lake Øyeren medium-chained paraffins dominate in the fish samples as well. Both short and medium-chained chlorinated paraffins have been found in the runoff from land-fills.</p> <p>It is presumed that the most important product areas are insulation/sealants/glue and imported PVC. The direct effects on human health are greatest for its uses in metalworking, however this is only a working environment problem and it is not incorporated into consumer products. The major problem is a general spreading of MCCP to the environment from many different products.</p>		

4) Occupational use

- Lubricants for metalworking
- Polyester for lifeboat production

Application areas only for occupational use will not be covered further in this overview.

5) Existing regulation of MCCP in consumer products

There is no existing regulation of MCCP in the EU or in Norway.

6) Alternatives

MCCP is used primarily as a fire retardant and softener. Alternatives exist for both application areas, however they are generally more expensive. For lubricants for metalworking, there are no satisfactory alternatives, but this is not a consumer product. Where MCCP is only used as a softener, DINP is a good alternative and not particularly more expensive. The alternatives as fire retardants exist, but are more expensive. In PVC, MCCP is primarily used only as a fire retardant in soft PVC. MCCP has not been registered in the Norwegian PVC industry. For paint and rubber/polymers (except PVC) long-chained chlorinated paraffins (LCCP) are an alternative as a softener, but they are more expensive.

7) Proposal for regulation

Medium-chained chlorinated paraffins (MCCP) are not regulated in the EU or in Norway at present. Short-chained chlorinated paraffins are strictly regulated in Norway and in the EU.

It is proposed that MCCP should be regulated because MCCP is on the priority list, is found in the environment and has been shown to exist in the food chain and in breast milk. MCCP is used in Norwegian production (but not in the Norwegian PVC industry), and in imported products. The use of MCCP has increased, probably as a result of a prohibition on PCB and SCCP. Alternatives to MCCP as a softener and fire retardant exist.

A prohibition is proposed on consumer products with more than 0.1 percent MCCP by weight in the product's homogeneous component parts.

The following examples of known application areas and products containing MCCP will be prohibited: PVC, paint, lacquer, surface treatment (primarily solvent-based), glue, insulation and sealants, polyester (softener/fire retardant), leather preservation and rubber. The list is not exhaustive; all areas of use within its scope will be covered by the prohibition.

As far as the regulations in the EEA Agreement and the WTO's regulations are concerned, the prohibition against MCCP in consumer products is regarded as appropriate and justified given the substance's specific properties that are hazardous to health and the environment combined with the specific risk the substance constitutes when it occurs in consumer products. In our opinion the health and environmental goals we are seeking to achieve justify the disadvantages regulation results in for the players, and other means are considered inappropriate.

In our opinion there are no specific legal regulations/total harmonisation requirements in the EEA chemicals regulations for MCCP that hinder the proposed regulation.

Socio-economic assessment

The proposal for regulation will reduce emissions of MCCP by approx half of the quantity

that is registered in the Norwegian Product Register, and it is expected that there will be a significant reduction of MCCP in imported articles. Replacement of MCCP with alternative fire retarding substances will involve increased costs, for example in sealants and putties. There is however other alternative means for sealing (for example mineral wool). Replacement of MCCP as a softener with alternative substances will not involve increased costs of any significance.

An extensive prohibition on the use of MCCP in consumer products would be the best means because one wants to reduce emissions significantly in the short-term. The proposal for regulation will involve some increased economic costs, but will give a significant reduction of the exposure of MCCP to the environment, as well as reducing the risk to human health. There are reasons to expect that the benefits are greater than the costs.

Assessment of impact associated with the regulation of hazardous substances in consumer products. Musk compounds

1) Substance or group of substances

Muskxylene, CAS No. 81-15-2

Muskketone, CAS No. 81-14-1

2) Known application areas

- air cleaners
- automobile wax
- floor and furniture polishing products
- washing and cleaning products
- fabric softeners
- cosmetics, perfume, toiletries and shampoo

The most important sources of emissions are washing agents and cosmetics. Among the consumer products, emissions from households, including from washing machines, showering and cleaning, are the most important contributors to problems involving human health and the environment. The musk compounds are in the process of being phased out in Norway and in Europe. The emissions are presumed to occur via municipal drainage systems. Total emissions in 2003 were 0.6 tons, which represents a reduction of 34% in relation to 1995.

Norwegian production/import/export

Musk compounds are not produced in Norway. Muskxylene and musk ketone are used to a very small degree in washing agents produced in Norway. The substances are in the process of being phased out in Norway and Europe. Can occur in products imported from countries outside the EU.

3) Description of human health and environmental risks

Muskxylene and musk ketone are very toxic for aquatic organisms, bioaccumulating and are persistent. Muskxylene is classified "Limited evidence of a carcinogenic effect" (R 40, Carc. Cat 3) and very toxic for aquatic organisms. It can cause long-term adverse effects in the aquatic environment (R 50/53).

According to the EU's risk assessment, exposure involving human health and the environment from consumer products occurs from emissions from the production of and the use of consumer products that contain muskxylene. The consumers can be exposed to muskxylene both by direct exposure from consumer products and by indirect exposure via the environment, for example through food. Muskxylene is stored in fatty tissues and is secreted in breast milk, with the level in breast milk having been reduced in the past decade. Muskxylene is a potential PBT (persistent, bioaccumulating and toxic) substance. The P and B criteria seem to be satisfied. The T criterion is satisfied due to Carc. Cat 3.

These substances fulfil all the criteria for the precautionary principle mentioned in the introduction.

The compounds have been found in aquatic environments, sludge and sediments, fish and mussels (in Europe). Samples of rainwater, blue mussels, reefs and sewer sludge did not show any nitro musk compounds.

4) Occupational use

- automobile wax
- floor and furniture polishing products

Application areas only for occupational areas will not be covered further in this overview.

5) Existing regulation of musk compounds in consumer products

Only regulations that deal with the products within the scope of the proposed ban are mentioned here.

- Cosmetics, perfume, toiletries and shampoo: the Norwegian Cosmetics Regulations, appendix 3: Substances with conditional authorisation in cosmetics and body care products (cf. section 6 in the regulations) laid down by the Ministry of Health and Care Services (formerly the Ministry of Health and Social Affairs)
Musketone: All cosmetic products with the exception of oral hygiene products
a) 1.4% in perfumes as a finished product (fine fragrance) b) 0.56% in "eau de toilette" and aftershave solutions c) 0.042% in other products.
All cosmetic products, with the exception of oral hygiene products a) 1.0% in perfumes as finished products (fine fragrance)
b) 0.4% in "eau de toilette" and aftershave solutions
c) 0.03% in other products.
- Washing agents, including car wax, floor and polishing agents with a cleaning effect: Norwegian Products Regulations, Section 3-10 (laid down by the Ministry of the Environment). Labelling requirements for musk compounds in washing agents are implemented in the Norwegian Products Regulations Section 3-10.
-

6) Alternatives

Used as a perfume substance. Can be replaced by other substances or possibly omitted.

7) Proposal for additional regulation

A prohibition is proposed on consumer products with more than 0.05 percent muskxylene and musktonone by weight. The following examples of known application areas and products containing muskxylen and musktonone will be prohibited: air cleaners, automobile wax and floor and furniture polishing products. The list is not exhaustive; all areas of use within its scope that do not fall under the exemptions will also be covered by the ban. It is proposed that the regulations listed under point 5 will be maintained as they are and they will not be changed by this ban.

As far as the regulations in the EEA Agreement and the WTO's regulations are concerned, the prohibition against muskxylene and musktonone in consumer products is regarded as appropriate and justified given the substance's specific properties that are hazardous to health and the environment combined with the specific risk the substance constitutes when it occurs in consumer products. In our opinion the health and environmental goals we are seeking to achieve justify the disadvantages regulation results in for the players, and other means are considered inappropriate.

In our opinion there are no specific legal regulations/total harmonisation requirements in the EEA chemicals regulations for muskxylene and musktonone that hinder the proposed regulation.

Socio-economic assessment

It is proposed that muskxylene and muskettone should be regulated because these substances are on the priority list, and have been found in the environment. The substances are strictly regulated in cosmetic products. We are not aware of the substances being used in Norwegian production.

Alternative aromatic substances exist, and musk compounds have no necessary function in the products. It would not be a problem to find suitable alternatives. An extensive prohibition on the use of musk compounds in consumer products would be the best means because one wants to reduce emissions significantly in the short-term, cf. the national target. A prohibition would reduce the incidence in the environment as well as reduce the risk to human health, so it is expected that the benefits will be greater than the costs.

Assessment of impact associated with the regulation of hazardous substances in consumer products. PFOA and their related compounds

1) Substance or group of substances

- Perfluorooctyl acid (PFOA) and individual salts and esters of PFOA, including the following: CAS No.: 335-67-1, PFOA CAS No. 3825-26-1, Sodium salt of PFOA, CAS No. 335-95-5, Potassium salt of PFOA, CAS No. 2395-00-8, Silver salt of PFOA, CAS No. 335-93-3, Acid Fluoride of PFOA, CAS No. 335-66-0, Methyl ester of PFOA, CAS No. 376-27-2, Ethyl ester of PFOA, CAS No. 3108-24-5

and

- Perfluorooctyl sulphonate (PFOS) and PFOS related compounds, chemical formula $C_8F_{17}SO_2X$ (X = OH, metallic salt, halogenide, amide or other derivatives including polymers)

(The regulation of PFOS is not proposed in this proposal, but the impact assessment is very much linked to corresponding assessments of PFOS. That is the reason why this substance is included in the discussion)

2) Known application areas for PFOA and PFOS

- Fire-fighting foam
- Textiles
- Preservatives
- Fluoropolymer and fluoroelastomer production
- Surface treatment
- Food packaging
- Hydraulic oil for aeroplanes
- Cosmetics
- Floor wax, polish
- Paint and lacquer

The list also contains application areas and products that are only for occupational use and they will not be covered by the prohibition on hazardous substances in consumer products.

According to the newest information from the fluoropolymer industry, around 90% of PFOA is used in fluoropolymer production, and the remaining 10% is used for surface treatment. There is no fluoropolymer production in Norway. Information from the Norwegian Product Register indicates that PFOA is not incorporated into products for which labelling is obligatory and which are available to consumers. According to the fluoropolymer industry, PFOA is not added to consumer products. PFOA was used in fire-fighting foam, cosmetics, oils, paint, lacquer, biocides and pesticides (Moody and Field, 2000). According to a study conducted by the Norwegian Food Safety Authority in 2006, perfluor compounds are not used in cardboard/paper packaging for so-called "fast food" in Norway, however in Europe and the US perfluor chemicals continue to be used for impregnation of paper packaging.

We are finding small quantities of PFOA, PFOS and their related compounds in textiles (up to 416 ng/g) and preservatives (up to 456 ng/g). The quantities are so low that we cannot presume that PFOS, PFOA or individual salts and esters of PFOA, have been added to the products. It probably only involves low levels of impurities. It is not acceptable that such serious hazardous substances as PFOS and PFOA are used in consumer products.

The most widespread application area for PFOS in Norway is special fire-fighting foam for extinguishing fires in oils and the like. The production of PFOS-containing fire-fighting foam ceased

in 2003. According to the industry, this fire-fighting foam is not sold for private use. For further information on PFOS, we refer to the impact assessment for the prohibition on PFOS in fire-fighting foam, textiles and preservatives.

3) Description of human health and environmental risks

PFOS and PFOA do degrade in the environment. PFOS and PFOA have been found everywhere in the environment. Evenset et al. (2006, Annex 2B) found PFOS and PFOA as the most common perfluorinated compound in sediments from the Ice Fjord on Svalbard. There have been no human activities at this location for 40 years, and the incidence is probably due to long-range transport of the substances.

Monitoring data shows that the substances are widely distributed in the environment in Nordic Countries including Norway (TemaNord 2004, Annex 3 and the Norwegian Pollution Control Authority 2005, Annex 4). The substances have been found in relatively high levels in human blood and in animals, including in the Arctic. A new the Norwegian Pollution Control Authority study (TA-2184/2006, Annex 5) of human blood samples from Northern Norway and Siberia shows PFOS and PFOA in all the samples. PFOS is the dominant perfluorinated compound, however we are also finding PFOA in these blood samples. There are no significant differences in the quantities of PFOS or PFOA in the blood samples from Northern Norway in comparison with those from Siberia.

In studies of mammals, the substances have been shown to be chronically toxic and injurious to reproduction. PFOA and PFOS are also suspected to be carcinogenic. Studies have also shown that PFOS and PFOA are toxic for aquatic organisms.

Norway has worked jointly with, among others, Sweden on the human health and environmental classification of PFOS and PFOA. It is being proposed that PFOS should be classified as toxic (T; R48/25), possible danger of cancer (Carc. Cat. 3; R40) and injurious to reproduction (Rep. Cat. 2; R61)

It is being proposed that PFOA should be classified as toxic (T; R48/23), carcinogenic (Carc. Cat 2; R45), and injurious to reproduction (Rep. Cat. 2: R61)

This substance fulfils all the criteria for the precautionary principle mentioned in the introduction.

4) Occupational use

- Fluoropolymer and fluoroelastomer production
- Surface treatment

It has been published previously that PFOS and PFOA are used, among other things, in food product packaging. There is some uncertainty as to whether this is still the case. The Norwegian Pollution Control Authority has not investigated this.

5) Existing regulation of PFOA in consumer products

There is no existing regulation of PFOA in the EU or in Norway

6) Alternatives

The US environmental agency, (theUS EPA) has got the large fluoropolymer producers in the US to obligate themselves to a 95% reduction in PFOA emissions from production and products before 2010, and 100% before 2015.

7) Proposal for regulation

PFOA are not currently regulated in the EU or Norway. The EU has adopted a directive which ban the use of PFOS in products. This directive enters in to force at the latest 27 June 2008. The EU Parliament desired to regulate PFOA together with PFOS. The arguments were that PFOA was a substance equally worthy of concern as PFOS. The proposal was not adopted, however the Commission will carry out additional risk assessments for PFOA and propose risk-reducing measures.

Norway adopted a ban against PFOS in fire fighting foam, textiles and impregnating agents on 23 March 2007.

PFOA are at present not regulated in the EU. As far as the regulations in the EEA Agreement and the WTO's regulations are concerned, the ban against PFOA in consumer products is regarded as appropriate and justified given the substance's specific properties that are hazardous to health and the environment combined with the specific risk the substance constitutes when it occurs in consumer products. In our opinion the health and environmental goals we are seeking to achieve justify the disadvantages regulation results in for the players, and other means are considered inappropriate.

In our opinion there are no specific legal regulations/total harmonisation requirements in the EEA chemicals regulations for PFOA that hinder the proposed regulation.

It is proposed that PFOA should be prohibited in consumer products with a limit value of 0.005 percent by weight and 1 microgram pr square metre in textiles and coated material.

The proposal is justified on the basis of PFOA's extremely serious human health and environmental properties. PFOA is found everywhere in the environment and in human blood samples around the world.

The following examples of known application areas and products containing PFOA will be prohibited: Textiles, preservatives, floor wax and polish and also paint and lacquer. The list is not exhaustive; all areas of use within its scope that do not fall under the exemptions will also be covered by the prohibition.

We have no information suggesting intended use of PFOA in consumer products in Norway today, however a prohibition would prevent such from being able to occur in the future. The proposed limit value in textiles will prevent placing textiles containing PFOA on the market.

Socio-economic assessment

An extensive prohibition on the use of PFOA in consumer products will be the best means of achieving this, and there will be no costs associated with this proposal. The socio-economic benefit is thus expected to be greater than the costs.

Assessment of impact associated with the regulation of hazardous substances in consumer products. Selected surfactants (Cationic surfactants)

2) Substance or group of substances

Cationic surfactants:

- a. DTDMAC, CAS No. 68783-78-8
- b. DODMAC/DSDMAC, CAS No. 107-64-2
- c. DHTDMAC, CAS No. 61789-80-8
- d.

2) Known application areas:

They are used as softeners in:

- auto care agents/auto wax
- boat putty
- floor wax
- laundry rinse agents *
- washing and cleaning agents*
- cosmetics, for example hair conditioner

*The washing agent regulations regulate the use of surfactants in washing and cleaning agents, laundry rinse agents and auto care agents with a cleansing effect.

The application areas that are consumer products and which are the most important contributors to the human health and environmental problems are cleaning agents and auto care agents. Emissions of cationic surfactants have been reduced significantly since 1995. Emissions for 2005 are presumed to be less than 1 ton. Consumption of surfactants was approx. 5.5 tons in 2003.

The surfactants are not produced in Norway, but are imported either as raw materials or in finished products.

The list also contains application areas and products that are only for occupational use and they will not be covered by the prohibition on use in consumer products.

3) Description of human health and environmental risks

Surfactants that are both water and fat soluble. The cationic surfactants are very toxic for aquatic organisms, and not very degradable. Consumers can be exposed via absorption through the skin. Exposure via the environment can occur via drinking water and vegetation.

The selected surfactants fulfil all the criteria for the precautionary principle mentioned in the introduction.

4) Occupational use

- washing and cleaning agents

Application areas for occupational use will not be covered further in this overview.

5) Existing regulation of the selected surfactants in consumer products

Only regulations that deal with the products within the scope of the proposed prohibition are mentioned

The washing agent regulations regulate the use of cationic surfactants in all washing agents that have a washing or cleansing effect. It is forbidden to use surfactants that do not comply with the requirements for degradability. The regulations are implemented in section 3-10, with appendixes, of the Norwegian Product Regulations, laid down by the Ministry of the Environment.

6) Alternatives

There exist other types of surfactants (easily degradable) that can be used. Other types of surfactants are used in Norwegian production of washing agents.

7) Proposal for additional regulation

A ban is proposed on consumer products with a total incidence of more than 0.01 percent by weight of the three surfactants concerned.

The following examples of known application areas and products containing the three surfactants concerned will be prohibited: auto care agents/auto wax, boat putty and floor wax. The list is not exhaustive; all areas of use within its scope that do not fall under the exemptions will also be covered by the prohibition. It is proposed that the regulations listed under point 5 will be maintained as they are and they will not be changed by this prohibition.

As far as the regulations in the EEA Agreement and the WTO's regulations are concerned, the prohibition on selected surfactants in consumer products is regarded as appropriate and justified given the substance's specific properties that are hazardous to health and the environment combined with the specific risk the substance constitutes when it occurs in consumer products. In our opinion the health and environmental goals we are seeking to achieve justify the disadvantages regulation results in for the players, and other means are considered inappropriate.

Beyond washing agents there are in our opinion no specific legal regulations/total harmonisation requirements in the EEA chemicals regulations for selected surfactants that hinder the proposed regulation.

Socio-economic assessment

It is proposed that cationic surfactants, DODMAC/DSDMAC, DHTMAC and DHTDMAC should be further regulated because these substances are on the priority list, and they have been found in the environment. They are used to a small degree in Norwegian production, but can occur in imported products. The substances are strictly regulated in washing and cleaning agents that are covered by the Washing Agent Regulations.

An extensive prohibition on the use of selected surfactants in consumer products would be the best means because one wants to reduce emissions significantly in the short-term, cf. the national target. The selected surfactants can be replaced in washing and cleaning agents. It thus ought to be possible to find alternatives in products that do not have a cleansing effect and which would be covered by the proposed prohibition.

A prohibition would reduce the incidence in the environment and reduce the risk to human health, so the benefits are expected to be greater than the costs associated with the proposed regulation.

Assessment of impact associated with the regulation of hazardous substances in consumer products. Triclosan

3) Substance or group of substances

Triclosan, CAS No. 3380-34-5

2) Known application areas

- Textiles (antibacterial agent in, among other things, athletics socks, cycling pants, loose shoe soles, shoe care agents)
- Plastic products (including breadboards, canvases, fabrics in baby carriages, rainwear for children)
- Paint
- Cosmetics and hygiene articles (including toothpaste, mouthwash, deodorants, soap, foot spray)
- Animal care agents
- Biocides

Registered quantities in Norway (import and export) have been reduced from 1.1 tons in 1998 to 0.01 tons in 2003. 1-2 tons of triclosan are used in cosmetics. Triclosan in articles is not included in the registered quantities.

3) Description of human health and environmental risks

Triclosan is classified as an irritant (Xi) and harmful to the environment (N) with risk statements R 36/38 (irritates the eyes and skin) and R 50/53 (very toxic for aquatic organisms, can cause undesirable long-term effects in the environment). The substance has the lowest percentage limit with respect to the environment (0.25%). Triclosan can develop resistance to antibiotics in bacteria. The substance is extremely toxic for algae (L(E)C50 in the range 0.1-1.0 µg/l) and has a high bioaccumulation potential (BCF values in the range of 2500 to 8400). Since triclosan exhibits an antibacterial effect, the ready biodegradability test is not relevant. "Inherent" degradability test results are difficult to interpret since triclosan is adsorbed to sludge.

Triclosan has been found in all sediment samples that have been analysed in Norway (The Norwegian Pollution Control Authority 2004, Annex 1). The concentration is higher in sediment from municipal landfills and in Drammen Fjord, and lower in sediment from Lake Mjøsa and the Drammen River. The concentration of triclosan in blue mussels and cod liver seems to be low, with the exception of somewhat higher levels in cod liver from Ullerøy. Triclosan has also been found in sludge from a number of municipal waste water treatment plants along Oslo Fjord. In Sweden, triclosan has been found in the air in addition to having been found in sediment and sludge. This indicates that triclosan is spread both via water and via the air. Triclosan has been found in relatively high levels in moose livers and in fish in Sweden. In addition, triclosan has been found in breast milk. The effects from point sources are thought to be less significant, whereas the effects from households are thought to be strong with respect to the levels of triclosan that has been found in the environment.

No risk assessment is available for triclosan in the EU existing program. The EU scientific committee on consumer products (SCCP) has made an assessment of the substance and recognize a great uncertainty regarding the antibiotic resistance. They ask for more

information on effects and they are of the opinion that it is a matter of urgency because triclosan has been identified in breast milk.

Triclosan has previously been assessed to be a candidate PBT (persistent, bioaccumulating and toxic) substance, but has not been evaluated further with respect to PBT because no relevant degradability tests were available. It could not be assessed whether the P criteria had been fulfilled. Triclosan does however fulfil the T and B/vB criteria. Since widespread occurrence of triclosan has been shown in the environment, such indicates that the substance is not easily degradable. This data, the possibility for the development of resistance to antibiotics in bacteria and that consumer products are probably the largest source of the occurrences in the environment indicate that the criteria for the generation target have been fulfilled. Triclosan in consumer products ought to be regulated.

This substance fulfils all the criteria for the precautionary principle mentioned in the introduction.

4) Occupational use

Biocides. Triclosan has been listed and is part of an assessment programme under the biocide directive. In the long-term triclosan will be regulated by the Norwegian Biocide Regulations when it is marketed as a biocide. These application areas will not be covered further in this overview.

5) Existing regulation of triclosan in consumer products

Only regulations that deal with the products within the scope of the proposed prohibition are mentioned here.

- Cosmetics and hygiene articles: the Norwegian Cosmetics Regulations, appendix 3: Substances with conditional authorisation in cosmetics and body care products (cf. section 6 in the regulations); soaps and products that are rinsed out after use / other products: limit values 0.5% / 0.3% (laid down by the Ministry of Health and Care Services (formerly the Ministry of Health and Social Affairs)).
-

6) Alternatives

Used as an antibacterial agent in textiles and plastic products. In most cases it can be replaced by other substances or possibly omitted.

7) Proposal for additional regulation

Triclosan in cosmetics are regulated in specific regulations that are based exclusively on health considerations. To begin with, exemptions will be made from the extensive prohibition on hazardous substances in consumer products containing triclosan that are regulated in the Norwegian Cosmetics Regulations. The environmental protection authorities will, at a later date, assess whether or not there is a need and opportunity for even stricter regulation of triclosan in cosmetics on the basis of environmental considerations.

An assessment is being made about whether or not other means can be used to reduce emissions of triclosan.

As far as the regulations in the EEA Agreement and the WTO's regulations are concerned, the prohibition on triclosan in consumer products is regarded as appropriate and justified given the substance's specific properties that are hazardous to health and the environment combined with the specific risk the substance constitutes when it occurs in consumer products. In our

opinion the health and environmental goals we are seeking to achieve justify the disadvantages regulation results in for the players.

In our opinion there are no specific legal regulations/total harmonisation requirements in the EEA chemicals regulations for triclosan that hinder the proposed regulation.

It is proposed that triclosan should be regulated because the substance fulfils the T and B/vB criteria. Since widespread occurrence of triclosan has been shown in the environment, such indicates that the substance is not easily degradable. There is a possibility for the development of resistance to antibiotics in bacteria. The largest source of emissions is presumed to be consumer products.

A prohibition is proposed on consumer products with more than 0.001 percent triclosan by weight.

The following examples of known application areas and products containing triclosan will be prohibited: Textiles, plastic articles and paint. The list is not exhaustive; all areas of use within its scope that do not fall under the exemptions will also be covered by the prohibition. It is proposed that the regulations listed under point 5 will be maintained as they are and they will not be changed by this prohibition.

Socio-economic assessment

Triclosan has no necessary function in most products. A prohibition would reduce its incidence in the environment and reduce the risk to human health, so it is expected that the benefits will be greater than the costs of the proposed regulation. Other means may also be socio-economically profitable with respect to emissions of triclosan.

Assessment of impact associated with the regulation of hazardous substances in consumer products. Pentachlorophenol

1) Substance or group of substances

Pentachlorophenol (PCP), CAS No. 87-86-5

2) Known application areas

- Imported impregnated woodwork (pallets with impregnated preparedness materials in the Norwegian Armed Forces)
- Imported impregnated textiles (occurs in awnings from Asia)
- Can occur in imported articles such as treated wood, fibre and fabric products, from countries outside the EU (for example possibly in decorative objects, rattan furniture, etc.)
- Leather

Pentachlorophenol (PCP) is banned as biocide in Norway and EU. PCP is not registered in the Norwegian Product Register. PCP was used previously as a slime control agent in the paper industry. It is not used in Norwegian production today. Can occur in imported articles.

The list also contains application areas/products that are only for occupational use and they will not be covered by the prohibition on use in consumer products.

3) Description of human health and environmental risks

A risk assessment for pentachlorophenol in the EU is available.

Pentachlorophenol (PCP) is very toxic, persistent and bioaccumulates in organisms. PCP in addition is carcinogenic and very toxic when inhaled. Under certain conditions the substance can give rise to the creation of dioxins. Pentachlorophenol is persistent in the environment and bioaccumulates in organisms. The substance has been classified as very toxic for aquatic organisms and can cause undesirable long-term effects in the aquatic environment.

This substance fulfils all the criteria for the precautionary principle mentioned in the introduction.

Pentachlorophenol is absorbed to particles in the soil, water and air and can be spread across long distances. Pentachlorophenol evaporates easily and is transported through the atmosphere. In areas with a cool climate, the substance condenses and is deposited in the environment. Some part of the pentachlorophenol in the Norwegian environment is probably deposited in consequence of transport through the atmosphere. In the Arctic, pentachlorophenol has been found in the air, freshwater, seawater, ice and fish.

4) Occupational use

- Preparedness materials in the Norwegian Armed Forces

Application areas for occupational use will not be covered further in this overview.

5) Existing regulation of pentachlorophenol in consumer products

Only regulations that deal with the products within the scope of the proposed prohibition are mentioned here.

- Cosmetics: the Norwegian Cosmetics Regulations, appendix IIB: Banned, laid down by the Ministry of Health and Care Services (formerly the Ministry of Health and Social Affairs)
- Products: Pentachlorophenol is currently banned in substances and preparations in containing more than 0.1 percent by weight (section 2-10 of the Norwegian Product Regulations), and it is also regulated in leather and textiles (section 3-4), laid down by the Ministry of the Environment

6) Alternatives

The substance is not used at present in Norwegian production. Hence there are satisfactory alternatives.

7) Proposal for additional regulation

It is proposed to prohibit consumer products with more than 0.1 percent pentachlorophenol by weight in homogenous parts of the product. The following examples of known application areas and products containing PCP will be prohibited: impregnated wood items and painted products. The list is not exhaustive; all areas of use within its scope that do not fall under the exemptions will also be covered by the prohibition. It is proposed that the regulations listed under point 5 will be maintained as they are and they will not be changed by this prohibition.

As far as the regulations in the EEA Agreement and the WTO's regulations are concerned, the prohibition on pentachlorophenol in consumer products is regarded as appropriate and justified given the substance's specific properties that are hazardous to health and the environment combined with the specific risk the substance constitutes when it occurs in consumer products. In our opinion the health and environmental goals we are seeking to achieve justify the disadvantages regulation results in for the players, and other means are considered inappropriate.

In our opinion there are no specific legal regulations/total harmonisation requirements in the EEA chemicals regulations for pentachlorophenol that hinder the proposed regulation.

Socio-economic assessment

It is proposed that pentachlorophenol should be further regulated. The substance fulfils the toxicity and bioaccumulating criteria. PCP is already being regulated in substances and preparations, as well as in leather and textiles. It is not being used in Norwegian production, but can occur in imported products, particularly wood items.

An expanded prohibition would involve articles also being covered, and reduce the incidence in the environment, as well as reduce the risk to human health. The prohibition would contribute to the avoidance of any possible future use. The primary purpose of expanded regulation is to fill gaps in the existing regulations and make sure that the emissions will stop. The substance occurs mainly in imported articles. Most manufacturers have already found alternatives to PCP in articles. The costs of an expanded prohibition would thus not be significant. We assume that the benefits are greater than the costs.

Assessment of impact associated with the regulation of hazardous substances in consumer products. Tributyltin and triphenyltin compounds

1) Substance or group of substances

Tributyltin and triphenyltin compounds (TBT and TPT)

2) Known application areas

- Imported impregnated wood items (window frames, door frames, garden furnitures)
- Imported impregnated textiles for outdoor use

TBT and TPT are banned as biocides in Norway and EU. TPT is not registered in the Norwegian Product Register. Small quantities of TBT have been registered in the Norwegian Product Register, less than 10 kg. It is not used in Norwegian production today. Can occur in imported articles.

3) Description of human health and environmental risks

There is no EU risk assessment available for TBT and TPT.

TBT and TPT are classified as harmful to the environment and are very toxic to aquatic organisms. The substances are also quite toxic to warm-blooded animals. In addition, they cause undesirable long-term effects in the aquatic environment because they are persistent and accumulate in organisms. These substances therefore fulfil the PBT-criteria (toxic, bioaccumulating and persistent).

TBT brings about imposex in snails. Imposex is the formation of male genitalia on female snails, something which is probably due to altered levels of sex hormones. The development occurs gradually and can in the end lead to sterility. In harbour areas in Europe, entire populations purple snails have been threatened due to imposex.

TBT and TPT are classified as toxic to humans. TBT can cause serious injuries to human health with prolonged exposure.

These substances fulfil all the criteria for the precautionary principle mentioned in the introduction.

Concentrations of tin organic compounds have been measured from stations along the coast. The compounds appear in elevated concentrations in sediments near shipyards, marinas and busy harbours and shipping lanes. Elevated levels of TBT have been ascertained in blue mussels and purple snails. Damage has been observed to reproductive organs in snails in subjected locations, however damages have also been observed far away from point sources, in areas with a high level of shipping activity. Annual monitoring since 1997 of the TBT levels in snails and blue mussels from outer Oslo Fjord and the Haugesund area show a weak improvement.

4) Occupational use

Unknown

5) Existing regulation of TBT and TPT in consumer products

Only regulations that deal with the products within the scope of the proposed prohibition are mentioned here.

TBT/TPT is currently totally banned in substances and preparations (section 2-8, first subsection, of the Norwegian Product Regulations), laid down by the Ministry of the Environment

6) Alternatives

The substances are currently not utilised in Norwegian production. There are therefore satisfactory alternatives.

7) Proposal for additional regulation

The substance is almost totally banned today, and no EU regulation that would be a legal obstacle to a total ban. The low limiting value that is being proposed for TBT/TPT (0.001 percent by weight) is presumed to not involve a softening up of the current ban without a limiting value.

As far as the regulations in the EEA Agreement and the WTO's regulations are concerned, the ban against TBT/TPT in consumer products is regarded as appropriate and justified given the substance's specific properties that are hazardous to health and the environment combined with the specific risk the substance constitutes when it occurs in consumer products. In our opinion the health and environmental goals we are seeking to achieve justify the disadvantages regulation results in for the players, and other means are considered inappropriate.

In our opinion there are no specific legal regulations/total harmonisation requirements in the EEA chemicals regulations for TBT/TPT that hinder the proposed regulation.

The following examples of known application areas and products containing TBT/TPT will be prohibited: Impregnated wood items (including window frames, door frames, garden furniture) and impregnated textiles for outdoor use. The list is not exhaustive; all areas of use within its scope that do not fall under the exemptions will also be covered by the prohibition. It is proposed that the regulations listed under point 5 will be maintained as they are and they will not be changed by this prohibition.

It is proposed that TBT/TPT should be further regulated. The substances fulfil the T and B/vB criteria. TBT/TPT is already regulated in substances and preparations. Can occur in imported articles, particularly wood products.

A ban is proposed on consumer products with more than 0.001 percent TBT/TPT by weight in homogenous parts of the product.

Socio-economic assessment

An extensive prohibition on the use of TBT/TPT in consumer products is the most appropriate mean to make sure that the emissions will stop. An expanded prohibition would involve articles also being covered, and reduce the incidence in the environment, as well as reduce the risk to human health. A prohibition would contribute to the avoidance of any possible future use. The primary purpose of expanded regulation is to fill gaps in the existing regulations. The substance occurs mainly in imported articles. Most manufacturers have already found alternatives to TBT/TPT in articles. The costs of an expanded prohibition would thus not be significant. The socio-economic benefits of the proposed regulation are assumed to be greater than the costs.

Assessment of impact associated with the regulation of hazardous substances in consumer products. Hexabromocyclododecane (HBCDD)

1) Substance or group of substances

Hexabromocyclododecane (HBCDD)

2) Known application areas

HBCDD is used in, among other things, the following product groups

- EE products
- Means of transport
- Construction materials (cellular rubber, insulation materials - EPS/XPS, glue/lacquer/joint filler, wet room panels, special products)
- Textiles
- Granulate (only for occupational use – export)

The list can also contain application areas/products that are only for occupational use and they will not be covered by the prohibition on HBCDD in consumer products.

Of the total of approx. 70 different brominated flame retardants, the three substances named decabromodiphenyl ether (deca-BDE), hexabromocyclododecane (HBCDD) and tetrabromobisphenol-A (TBBPA) constitute the largest portion. The total consumption of brominated flame retardants in Norway (includes in total around 70 different compounds) was registered in the Norwegian Product Register in 270-300 tons in 2003. The consumption has increased by an order of magnitude of 5 times during the period of 1995 – 2003.

This is distributed as 210-220 tons in EE products, of which only small quantities are presumed to be HBCDD. HBCDD is used primarily in the production of cabinets in EE products. In means of transport, 30-50 tons of brominated flame retardants have been registered. Approx. 10-17 tons of this is presumed to be HBCDD. Approx. 30 tons of brominated flame retardants were registered in construction products. In 2005 a total of approx. 4 tons of HBCDD was registered as used in insulation materials (for building houses and roads, etc.). Cellular rubber in the Norwegian market contains approx. 25 tons of brominated flame retardants, and it is presumed that approx. 6-8 tons of this is HBCDD. There are reasons to presume that HBCDD is found in some imported products that we do not have an overview of.

Number of players in Norway/large or small / Norwegian production/import/export

There are significant imports of means of transport and EE products into Norway. There is little production of means of transport in Norway, however there are many importers. There are some manufacturers of construction materials and EE products in Norway, and many importers.

Norwegian production and use of construction products (insulation materials) with HBCDD has been significantly reduced since 1992. HBCDD is used in Norwegian production of granulate, however this is exported for use in the professional market. Norwegian production of cellular rubber has ceased, but it is expected that imports will increase in the future. Annual consumption in Norway in 2004 was approx. 500 tons. It is presumed that approx. 25-30% of

this contains HBCDD. EE products contain only small amounts of HBCDD, but it can occur in many imported products such as inexpensive consumer electronics and electrical toys produced in Asia, but it is difficult to estimate the extent. Large quantities of HBCDD have been used previously in the production of furniture fabrics. It is said that this use has now ceased, but it cannot be excluded that imported products could contain HBCDD.

HBCDD is primarily used additively, i.e. the substance does not enter into a chemical reaction with the other components of the products. Substances that are applied additively will normally have a greater potential to leak out of the products than those that are used reactively.

3) Description of human health and environmental risks

HBCDD is very toxic to aquatic organisms, persistent and may cause long-term adverse effects in the aquatic environment. In the EU's working group for classification and labelling, no decision has been made on the proposal for a human health classification for HBCDD, however the Rapporteur has proposed that the substance should be classified and labelled with R 33 "Danger of cumulative effects" and R64 "May cause harm to breast-fed babies". In June 2003 it was agreed that the substance should be classified and labelled as dangerous for the environment with N; R 50-53 and assigned specific lower concentration limits down to 0.025%. The classification has not been finally determined because classification with respect to human health is awaited.

Potential for long-range transport. Measured in sediments, plants and animals. Found in animals higher up in the food chain, far from point sources and in the Arctic.

Emissions from products: Emissions of brominated flame retardants from products are estimated to be 1-2 tons in 2003.

EU risk assessment: HBCDD has been found in remote areas; in the north of Sweden and Finland far from potential sources, in fish in mountain lakes in Switzerland, in blue mussels from Lofoten and Varanger, in cod liver from Northern Norway, in cod and ringed seals from Svalbard, in marine birds and birds' eggs from Northern Norway, in polar bears from Greenland and Svalbard. These findings indicate long-range transport of HBCDD. The measured quantities cannot be explained by the use of products that contain HBCDD in the small populations in these areas. Since the highest concentration of HBCDD is measured in marine mammals, this indicates that HBCDD biomagnifies. Newer data indicates that the levels in marine mammals are increasing. Also a Norwegian study of the occurrence of a.o. HBCDD over a period of 20 years in eggs of Arctic seabird species from Northern Norway and Svalbard shows increasing levels from 1983 to 2003 (SPFO-Report 942/2005, Annex 6). The persistence of HBCDD is documented by the fact that it can be found in remote areas and accumulates in top predators. The EU working group on PBT substances has regarded HBCDD as a PBT (persistent, bioaccumulative and toxic) substance.

This substance fulfils all the criteria for the precautionary principle mentioned in the introduction.

4) Occupational use

Granulate that is exported

Application areas only for occupational use will not be covered further in this overview.

5) Existing regulation of HBCDD in consumer products

HBCDD is not regulated in consumer products in EU or Norway.

6) Alternatives

It has so far proved to be difficult to find alternatives. When there is a need to make flame retardant insulation materials (EPS/XPS) flame retardants that are effective at low concentrations are required. The products have a very low specific gravity. For some application areas other construction products can be used, for example glass wadding, mineral wool, etc. Requirements for fire safety at construction sites can also be satisfied with the use of other working methodologies and procedures.

In many cases a different type of flame retardant can be used or changes can be made to the product's composition and/or design. No other flame retardant exists that can fully replace HBCDD in all areas, but there are other different brominated and non-brominated flame retardants that can be used in textiles, EE products and cellular rubber. The costs of such changes will vary in relation to precisely which changes are being performed and whether other changes are being performed at the same time. Other flame retardants can be both less expensive as well as more expensive than HBCDD.

7) Proposal for regulation

The EU working group on PBT substances has regarded HBCDD as a PBT substance. The persistence of HBCDD is documented by the fact that it can be found in remote areas and accumulates in top predators. In addition to that the substance is bioaccumulating and toxic.

The Norwegian Pollution Control Authority is proposing a prohibition on consumer products with more than 0.1 percent HBCDD by weight in the product's homogenous component parts.

Examples of known application areas for HBCDD that will be prohibited are EE products, construction materials (cellular rubber, insulation materials - EPS/XPS, glue/lacquer/joint filler, wet room panels, special products) and textiles. The use in transport means is out of the scope of the proposed regulation. The list is not exhaustive and all application areas that is not included by the exemptions, are comprised by the prohibition.

As far as the regulations in the EEA Agreement and the WTO's regulations are concerned, the prohibition on HBCDD in consumer products is regarded as appropriate and justified given the substance's specific properties that are hazardous to health and the environment combined with the specific risk the substance constitutes when it occurs in consumer products. In our opinion the health and environmental goals we are seeking to achieve justify the disadvantages regulation results in for the players, and other means are considered inappropriate.

In our opinion there are no specific legal regulations/total harmonisation requirements in the EEA chemicals regulations for HBCDD that hinder the proposed regulation.

Socio-economic assessment

For an extensive prohibition, it is expected that the greatest costs will be connected with a prohibition on granulate containing HBCDD (export of semi-finished goods) and use in means of transport. The concerned granulate is not a consumer product and will in addition to means of transport be exempted in the proposed regulations. These two application areas will thus not be covered by the regulations.

For some special products for pipe insulation (cellular rubber) the alternatives can be somewhat more expensive. We do not expect, however, that the regulations will involve significant costs.

An extensive prohibition on the use of HBCDD in consumer products would be the best means because one wants to reduce emissions significantly in the short-term. The socio-economic benefit of the proposed regulation is thus expected to be greater than the costs.

Assessment of impact associated with the regulation of hazardous substances in consumer products. Tetrabromobisphenol A (TBBPA)

2) Substance or group of substances

Tetrabromobisphenol A (TBBPA)

2) Known application areas

TBBPA is used in, among other things, the following product groups

- EE products
- Means of transport
- Different plastic products

Of the total of approx. 70 different brominated flame retardants, the three substances named decabromodiphenyl ether (deca-BDE), hexabromocyclododecane (HBCDD) and tetrabromobisphenol A (TBBPA) constitute the largest portion. TBBPA is the most-used brominated flame retardant on a global basis.

The total consumption of brominated flame retardants in Norway (includes in total around 70 different compounds) was registered in the Norwegian Product Register as 270-300 tons in 2003. The consumption has increased by an order of magnitude of 5 times during the period of 1995 – 2003.

This is distributed as 210-220 tons in EE products, of which approx. 190 tons is presumed to be TBBPA. A total of 33-37 tons of this is presumed to be used as an additive; however it is difficult to get reliable figures. TBBPA is used primarily in the production of printed circuit boards in EE products. In means of transport, 30-50 tons of brominated flame retardants have been registered. Approx. 3-5 tons of this is presumed to be TBBPA. (Approx. 30 tons of brominated flame retardants are registered in construction products; however, these are mainly substances other than TBBPA).

Number of players in Norway/large or small / Norwegian production/import/export

There are significant imports of means of transport and EE products into Norway. There is little production of means of transport in Norway, however there are many importers. There are some producers of EE products in Norway, and many importers.

There are significant imports of circuit board laminate, finished circuit boards and circuit boards in finished products. Correspondingly, there are exports of finished circuit boards. In circuit boards, TBBPA is primarily used reactively. In cabinets, other EE products and in plastic products, TBBPA is usually used additively.

TBBPA is really primarily used reactively, however the scope of the additive use is more uncertain and it seems to be increasing. There are reasons to presume that TBBPA used as an additive exists in many imported products such as inexpensive consumer electronics and electrical toys produced in Asia, however it is difficult to survey the extent. With additive use, the substance will not enter into a chemical reaction with the raw material as is the case with reactive use. Substances that are applied additively will normally have a greater potential to

leak out of the products than those that are used reactively.

The list does also contain application areas and products that are only for occupational use and they will not be covered by the prohibition of certain hazardous substances in consumer products.

3) Description of human health and environmental risks

TBBPA is very toxic for aquatic organisms, and may cause long-term adverse effects in the aquatic environment. Acutely toxic for fish and daphnia and persistent. The P criterion in the PBT (persistent, bioaccumulating and toxic) assessment seems to be fulfilled.

Bioconcentration factor (BCF>100, fish).

this substance fulfils all the criteria for use of the precautionary principle mentioned in the introduction.

EU risk assessment - proposal for classification with respect to environment: Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.

R 50/53. Emission to the environment can occur both to the air (vapour, dust) and from sewage/wastewater. Sources of emissions are the production sites, but also the end products (for example plastic components) during use and final deposition. The level of free residual is quite low, so that the direct exposure of consumers is probably insignificant. However the substance has been found in blood in the general population in Norway and increasing levels were found during the period spanning 1986-1999. A study showed that the levels were the highest in the 0-4 year old age group. In a study from 2006, TBBPA was found in one of the blood samples from pregnant Norwegian women in Bodø, whereas it was not found in pregnant women from Taimyr in Russia. TBBPA has also been found in samples of breast milk in Norway and other countries. According to the EU's risk assessment, the exposure of newborns to TBBPA is expected to be quite low.

A screening study from 2002 found TBBPA in moss samples. That indicates that the substance can be transported a long distance via the air. Measured in sediments, plants and animals. TBBPA has been found higher up in the food chain, far from point sources and in the Arctic, including in birds of prey and eggs of birds of prey (for example the peregrine falcon and golden eagle) and in marine mammals (porpoise).

Emissions from products: Emissions of brominated flame retardants from products are estimated to be 1-2 tons in 2003.

Under certain environmental conditions TBBPA can degrade to other harmful substances, for example bisphenol A, which is harmful to aquatic organisms since it has hormone disruptive effects. TBBPA leaks from EE waste and landfills. A screening study from 2004 showed that the substance is found many places in Norway, for example in leakage water from landfills, sediments (freshwater and marine) and in fish.

4) Occupational use

EE products that can be used in business enterprises, for example advanced control systems. Application areas only for occupational use will not be covered further in this overview.

5) Existing regulation of TBBPA in consumer products

TBBPA is not regulated in consumer products in EU or Norway.

6) Alternatives

In many cases a different type of flame retardant can be used or changes can be made to the product's composition and/or design. There is no other flame retardant that can completely replace TBBPA in all areas, but there are different brominated and non-brominated flame retardants that can be used. The costs of such changes will vary in relation to precisely which changes are being performed and whether other changes are being performed at the same time. Other flame retardants can be less expensive as well as more expensive than TBBPA. Halogen-free circuit boards are said to be approx. 30-40% more expensive than circuit boards with TBBPA. There is uncertainty concerning the availability of alternative flame retardants when it concerns the additive use of TBBPA in special types of plastic such as high impact polystyrene (HIPS) and acrylo-nitrile-butadiene-styrene (ABS) for cabinets.

7) Proposal for regulation

For TBBPA, the P criterion in the PBT assessment seems to be fulfilled. The substance occurs in EE products and means of transport, and is used both reactively and additively. Additive use appears to be increasing, essentially in imported EE products. Potential leakage to the environment increases with increased additive use.

It is proposed a prohibition on consumer products with more than 1 percent TBBPA by weight in the product's homogeneous component parts. Examples of known application areas for TBBPA that will be prohibited are EE products and different plastic products. The list is not exhaustive and all application areas that is not included by the exemptions, are comprised by the prohibition.

The primary purpose of the regulation is to regulate its use as an additive. With an extensive prohibition it is expected that the greatest expenses will be associated with a prohibition on use in circuit boards and means of transport, however by proposing a limiting value for TBBPA in products of 1% the intent is not to cover reactive use in circuit boards. In practice the portion of TBBPA in the circuit boards will be under 1%. There is some uncertainty associated with the extent of the additive use of TBBPA in imported electronic products. The industry has not provided specific feedback in the reference group meetings concerning the proposed prohibition representing any great problem. In addition, it is being proposed that means of transport will be exempted from the regulations.

As far as the regulations in the EEA Agreement and the WTO's regulations are concerned, the prohibition on TBBPA in consumer products is regarded as appropriate and justified given the substance's specific properties that are hazardous to health and the environment combined with the specific risk the substance constitutes when it occurs in consumer products. In our opinion the health and environmental goals we are seeking to achieve justify the disadvantages regulation results in for the players, and other means are considered inappropriate.

In our opinion there are no specific legal regulations/total harmonisation requirements in the EEA chemicals regulations for TBBPA that hinder the proposed regulation.

Socio-economic assessment

We thus does not expect that the regulations will involve significant costs. The socio-economic benefits of the proposed regulation are thus expected to be greater than the costs. An extensive prohibition on the use of TBBPA in consumer products would be the best means because one wants to reduce emissions significantly in the short-term.

