

Summary of consultative statements and SFT's proposal for regulation

SFT's assessment of follow-ups on the proposal for the individual substances

A summary of all the consultative comments for the individual substances is given in appendix 3 and the impact assessment for the substances is available in appendix 4.

Arsenic

Consultative comments

Many comments have been received on the proposal for a prohibition on an arsenic content of greater than 0.01 % by weight in homogeneous individual parts of the product, particularly from the ICT and electronics industry. The majority of the comments are connected with the use of gallium arsenide in components of electronic products. The consultative bodies are of the opinion that it is not possible to deliver electronics products that fulfil the requirements.

Japanese consultative bodies have forwarded industry standards and internal company guidelines for electronics where the limit value for arsenic is set to 0.1 %, as well as exemptions for semiconductors and copper foil for use in printed circuit boards. These standards and guidelines are used by the industry, among other things, for the purchasing of components from subcontractors. Strict requirements are posed for documentation that limit values are fulfilled. Requirements in the standards build on requirements and the exemptions in the RoHS Directive, but do also include requirements for substances that are not included in RoHS.

Arsenic is also used in the production of many types of special glass, such as optical glass (spectacle glasses and micro camera lenses) and in glass ceramics (stove tops, hearth glass and different types of technical glass). Furthermore, arsenic is contained in both stainless steel and tin. International standards permit arsenic as an impurity in tin up to 0.03%. We have also been informed of a change in the EU's Limitations Directive that makes an exemption for reuse of CCA-impregnated wood under certain preconditions (planned to be incorporated into Norwegian law during the course of 2008). More detailed consultative comments are described in appendix 3 (only available in Norwegian).

A number of consultative bodies, including the EU Commission and ESA, are of the opinion that it is not possible to regulate hazardous substances in electrical and electronic products (EE products) because such is subject to total harmonisation in the RoHS

Directive and in contrary to article 4 (1), even though arsenic is not specifically regulated in RoHS.

SFT's assessment

Previous surveys SFT has done of arsenic have not shown a comprehensive use of arsenic in EE products such as has emerged in the consultative statements. We were hence not aware of the comprehensive use when the proposal was formulated. Only a couple of weeks prior to the proposal being sent out for consultations we were made aware of this application area for arsenic. The limit being proposed for arsenic then was 0.01 % weight, which in our opinion was acceptable on the basis of the documentation that we had received from the industry at that point in time. The comments show that this limit value is too low. It has not been our intention to prohibit all electronics or stainless steel and tin, which many are of the opinion, would be the consequence of the proposal.

In SFT's interpretation, arsenic is not regulated in the applicable RoHS Directive as has been maintained in a number of the consultative comments. A harmonized EU directive must include both a free movement clause and a safeguard clause. The RoHS Directive includes neither of these, but rather a paragraph 4.1 entitled "prevention" that states that the Member States (MS) must see to it that EE products on the market do not include the substances that are specifically mentioned in this article, among others lead and mercury. This is in contrast to, for example REACH and classification and labelling which include both a free movement clause and a safeguard clause. We are thus of the opinion that arsenic is not regulated in the RoHS Directive. It is furthermore stated in the RoHS Directive that national rules that encompass these substances that are covered by the directive, and which were adopted before RoHS was adopted, may be maintained until it enters into force. Concerning substances other than those that are discussed in article 4.1 in the directive, there thus are good possibilities for national rules. The wording of the directive does not mention substances other than those that have been mentioned in article 4.1. This indicates quite clearly that the regulation of other substances has in fact not been harmonised. In paragraph 4.3 it is also stated that the Commission shall continue to work on banning other hazardous substances in EE products. We hence are of the opinion that it ought to be possible to argue in favour of additionally regulating arsenic in EE products and that individual countries may take the lead.

The consultative process shows that arsenic in electronics in particular is a significant source of the total content of arsenic in products. After arsenic was prohibited for use in wood impregnation, indications are that electronics comprises the greatest remaining source in products. Even though the quantities in each individual unit are not so large, it involves a large number of products. Thus the total quantity is significant, for example a total of 2.3 million mobile telephones were sold in Norway in 2007. There have been return systems established for EE products, but many small EE products and toys are not collected. Arsenic from discarded EE products may leak out to the environment if they are managed in a responsible manner. It thus is important to reduce the arsenic content in EE products where such is possible.

We have received a number of standards for EE products from Japanese consultative bodies. These standards are both internationally accepted standards and standards from a large manufacturer of components for EE products. Many manufacturers of EE products are familiar with these standards and there hence are products that fulfil the requirements, even though not all of the manufacturers are in a position to fulfil them. It thus also ought to be possible to obtain documentation showing that the products fulfil the given standards.

In the EU, arsenic is regulated in the Biocide Directive and in the Limitations Directive, especially impregnated wood. Furthermore, manufacturers who utilise arsenic in their production within the EU must register their use when obligations in REACH enter into force. Arsenic was notified as a wood protection agent under the Biocide Directive, however the application was not submitted and arsenic is now out of the programme and its use prohibited as a wood protective agent along with other biocide uses in the EU and Norway from 1 September 2006.

In contrast, the Biocide Directive does not encompass imported products, and they will be affected by REACH to a lesser degree. The consumer products that are encompassed by the prohibition are primarily all imported products and are not regulated in EU.

The RoHS Directive is being revised. In this connection, the Institute for Applied Ecology in Germany is currently working on an assignment from the EU Commission to assess precisely which substances are included in EE products, the risk to health and the environment posed by such, in precisely which components and what quantities they occur and what possible alternatives exist. A list of 46 substances, including arsenic, gallium arsenide and arsenic trioxide, has been sent out for consultation. The report was supposed to be published in April 2008, but has been somewhat delayed. An assessment will subsequently be made of whether new substances should be included in RoHS. Revision of RoHS is a process that has just started. Our experience with corresponding processes in the EU is that it takes a long time to bring them to a conclusion, and that it thus will take a long time before new substances are possibly included in the RoHS Directive.

In addition, Norway must include the exemption for reuse of CCA in the Norwegian Product Regulations as soon as possible.

SFT is proposing on the basis of the above to maintain the proposal regulating arsenic in consumer products, but is proposing in light of the consultation comments to differentiate the limits for different consumer products, i.e. maintain the proposal with a limit of 0.01 % by weight for consumer products exempting EE products. We are proposing raising the limit to 0.1 % by weight (1000 ppm) for EE products. In addition, some additional exemptions are being proposed for, among other things: steel, aluminium and copper alloys with limit values with respect to the RoHS Directive. We are of the opinion that with these changes the proposal is both justified and proportional in relation to the objectives that we wish to achieve.

Bisphenol A

Consultative comments:

Many comments have been received that refer to the EU's risk assessment of bisphenol A (BPA). The conclusion is that no risks to health or the environment exist with the use of or emissions from consumer products made with BPA as a raw material, and where it has been established that it is not necessary to prohibit or restrict the use of BPA in consumer products. There hence were a number who were of the opinion that SFT's impact assessment did not satisfy the criteria for good risk assessment, and that Norway is ignoring scientific data. They are of the opinion that Norway has no proof that the health of consumers is harmed by emissions of BPA. Furthermore, it was pointed out that the EU's experts at the EFSA (European Food Safety Authority) have reduced the margin of uncertainty associated with BPA and raised the TDI value (tolerable daily intake) from 0.01 to 0.05 mg/kg of body weight.

BPA will be discussed during REACH and is being discussed in connection with risk reduction strategy (RRS). It is being recommended that Norway wait until this work is finished.

BPA (as bisphenol A diglycidyl ether and its polymers) are found as residue in epoxy resin used in paint, approx. 0.02 – 0.04 %. It has been pointed out that no information has been given or impact statements prepared for alternatives to BPA or for its downstream products and that no satisfactory alternatives exist for BPA. Furthermore, it has been pointed out that the proposal for limit values has not been scientifically documented, and that they seem to be arbitrary. If Norway's proposal for regulation is implemented, it will have large financial and social consequences for Norwegian industry and Norwegian consumers.

On the other hand, there is one consultative body that desires a total prohibition on BPA in products for children less than 3 years of age and refers to the fact that two independent expert panels (EFSA and CERHR) have arrived at different conclusions with respect to BPA exposure. They also refer to possible synergistic effects.

SFT's assessment

More detailed documentation as well as the background for SFT's assessment of bisphenol A (BPA) is given in the impact assessment in appendix 4.

Production and consumption of BPA in the EU is extremely high, and has increased significantly in the last ten years, from 690,000 tons/year in the years 1996-1999 to 1,149,870 tons/year in 2005/2006.

SFT's proposal does not involve a total prohibition on BPA or consumer products that contain BPA. The proposal only sets a limit for acceptable residual monomer content (free BPA) in the products. The justification for this is to avoid possible emission of free

monomer of BPA in plastic into the environment or to expose consumers who use the products. It has not been the intention of the authorities to prohibit BPA in general or products made of BPA. SFT's analyses show a wide range of levels of free BPA in different types of products that have been analysed, and many of them are within the proposed limit values, i.e. they will be legal to sell with the proposed prohibition. However, products have been identified in the Norwegian market, including joint filler, children's mittens and travel items that in part contain somewhat rather high levels of freely available BPA. These products will not be legal to sell with the proposed prohibition. Such products are not included in the EU risk assessment.

BPA is classified as an irritant and may cause sensitisation by skin contact as well as harmful to reproduction (Rep Cat 3, R62; possible risk of impaired fertility). Endocrine disrupting effects (oestrogen effect) have been demonstrated in fish. BPA is harmful to aquatic organisms.

The EU has prepared a revised risk assessment for the environment (Final environmental addendum, draft for final written comment of September 2007). It documents that BPA has endocrine disrupting effects on fish. A conclusion i) is also continued; which means that there is a need for further testing and/or more information on the environment, in relation to possible effects on snails at concentrations lower than what is now being used for the risk characterisation. When the final results of the testing initiated by the authorities in the UK are available, the risk assessment will be revised under REACH. It is uncertain when these results will be available. With respect to the neurotoxic effects, there is still uncertainty concerning the lower threshold values for effects on the environment and in our view also for effects on health.

BPA is an endocrine disrupting substance. It was also pointed out in the risk assessment performed by the UK that simultaneous exposure to multiple endocrine disrupting (oestrogen) substances may give additive effects, this has not been captured in the current risk assessments. This is clearly a shortcoming.

Monitoring data shows that BPA has been found in sludge and sediments (silt) from Mjøsa, Drammenselva, Inner Drammen Fjord and in sediments along the Norwegian coast and consequently widespread in the Norwegian environment. Among other things, it has been demonstrated that BPA is present in freshwater fish in relatively high levels, which also is a source of exposure for humans. People who eat a lot of fish from areas with higher concentrations of BPA may be subjected to a higher exposure than the general population. In a newly published study, bisphenol A was also shown to be present in sediments from the Barents Sea.

Extremely little data exists for fish for the EU. There are some newer measurements from the Netherlands (Vethaak et al 2002), the values here are lower than the Norwegian values. SFT is of the opinion that the data is comprehensive for Norway (coverage includes Mjøsa, Vormå, Øyeren and Inner Drammen Fjord). The Norwegian measurement data has been sent to the reporter, and has now been included in the risk assessment. The reporter concludes that the measured levels in fish are of the same order

of magnitude as the calculated values, but it is recognised at the same time that some of the values measured for fish are higher than the calculated values. The reporter however deems the measurement data not to be sufficiently comprehensive, and since they can neither be allocated with certainty to a local or the regional scenario, the calculated values are used. We are of the opinion that the worst case values for fish (14 µg/kg wet weight) ought to be used in the calculation of human exposure via the environment in the regional scenario, in addition to the calculated one, in order to protect all sections of the population. This will have consequences for the risk assessment for humans exposed via the environment (Man Via Environment). When the worst case value of 14 µg/kg wet weight is used in the regional scenario, the regional exposure becomes higher in comparison to the regional exposure in the EU RAR draft of September 2007.

In our view there is still uncertainty concerning effects on health with respect to neurotoxic effects (effects on learning and memory in offspring). The substance has been classified as harmful to reproduction. It is uncertain when satisfactory data for neurotoxic effects will be available. We have demonstrated BPA content in mittens and found high values of the substance. When the threshold values for neurotoxic effects are applied in the risk assessment and exposure to BPA from mittens are included in the total exposure, the safety factor becomes 8, which is far under the recommended limit of 100.

A revised risk assessment of health (updated risk assessment, draft of November 2007) was discussed at TC NES IV (the EU's technical meeting) in December 2007. The results from a study of effects harmful to reproduction are included and the reporter concluded that the previously selected NOAEL (No Observed Adverse Effect Level) of 50 mg/kg bw/day would be retained and that there was no risk for consumers or humans exposed via the environment. Some studies have however demonstrated effects at lower concentrations, but these have been rejected by the reporter. Norway, Sweden and Denmark have commented that low-dose effects can not be ignored. Norway (in addition to Sweden and Denmark) are of the opinion that the lower limit values from applicable studies that show effects on learning and memory in offspring at extremely low doses must be used until possible new, adequate studies of neurotoxic effects are available.

The Nordic countries did not receive support from a majority at the meeting, which decided to complete the risk assessment without further testing. It was accepted however that a footnote should be inserted in the risk assessment stating that S, DK and N were of the opinion that neurotoxic effects have not been sufficiently taken into account at low doses, from 0.1 to 0.25 mg/kg body weight/day. In addition, the completely newly updated NTP (National Toxicology Program) assessment from November 2007 concludes that there are still concerns connected with possible neurotoxic effects of BPA and that further tests ought to be performed. This supports the assessments of N, S and DK that there continues to be uncertainty concerning the extent to which the risk assessment adequately takes possible low dose effects into account.

The Norwegian Scientific Committee for Food Safety (Norwegian Initials: VKM) was commissioned by the Norwegian Food Safety Authority to evaluate studies where a possible effect has been demonstrated in experiments on animals involving the

development of the nervous system of newborns. VKM concluded that there are significant deficiencies in the studies, but that the results from the studies also give reasons for concern. VKM is thus proposing that a new study should be performed to investigate possible effects on the development of the nervous system in newborns instead of changing the NOAEL value (No Observed Adverse Effect Level) of 5.0 mg/kg body weight/day that EFSA (European Food Safety Authority) uses in order to set the ADI (Acceptable Daily Intake). It will be at least 2-3 years before the results from a new study are ready. When the NOAEL value of 5.0 mg/kg body weight/day is compared with the child's exposure for bisphenol A from consumer products, food and the environment (0.013 mg/kg body weight/day) the safety factor becomes 380. Due to the uncertainty connected with possible neurotoxic effects in newborns upon exposure to bisphenol A, SFT is of the opinion that the safety factor is too low.

Furthermore, the Canadian authorities have performed a risk assessment of bisphenol A that currently is undergoing consultations. The risk assessment concludes that the level of bisphenol A in cans intended for food for small children must be lower or be replaced with less hazardous substances, and that a prohibition must be introduced on feeding bottles that contain bisphenol A. This assessment is based upon new studies that show toxic effects on the development of the nervous system and on the behaviour of test animals with doses that are close to the calculated bisphenol A exposure for newborns.

The largest manufacturer of plastic bottles has halted production of plastic bottles containing bisphenol A, and the largest retail chains no longer sell products of plastic for children's with bisphenol A.

In the US, the healthcare authorities have signalled a new attitude towards bisphenol A exposure.

SFT has analysed the content of free BPA in a number of products and recently supplemented such with further analyses in 2008. The limit values in the proposal have been proposed on the basis of the analysis.

We are proposing maintaining the limit value at 0.005 % by weight of free bisphenol A, but are removing the proposal to tighten the limit to 0.0025 after three years. On the basis of the analysis, a limit value of 0.005 % by weight will be adequate and there is very little extra to gain from tightening the limit after three years.

We are proposing on the basis of the above arguments to maintain the proposal on limiting freely available BPA in consumer products. We are proposing maintaining the limit value at 0.005 % by weight of free bisphenol A, but are removing the proposal to tighten the limit to 0.0025 after three years. SFT is of the opinion that the proposal is justified and that the regulation such as it has been formulated satisfies the requirement for proportionality.

Lead

Consultative comments

We have received several consultative statements saying that the proposed limit value of 0.01 % by weight is too strict. These apply for a number of application areas, for example tin, which contains up to 0.05 % lead, brass up to 4 % and steel up to 0.35%. Furthermore, some metals such as aluminium and copper can contain up to 0.4 and 4 % respectively. Both the RoHS (Restriction on hazardous substances in electrical and electronic equipment) and ELV (End of life vehicles) directives have differentiated limit values for lead in alloys. Small internal-combustion motors contain up to 40 % lead. Some special types of glass require the presence of lead in order to achieve their functionality, such as optical glass. Recycled glass may contain 0.03-0.06 % lead. Glass wool is produced from recycled glass and thus may contain 0.02 % lead. Solder also contain lead and we have received standards from Japan that encompass, among other things, EE products. Furthermore, the proposed limit value is 50 times lower than the classification limit and 10 times lower than the limit for lead in the RoHS Directive and the allowed quantity of lead in vehicles. It has been pointed out that the Norwegian proposal must be harmonised with the national Danish prohibition. Furthermore, the EU Commission makes reference to emission figures in the impact assessment and is of the opinion that the proposal is not proportional because it regulates only 2 % of the remaining lead emissions in Norway. The lead industry is of the opinion that no risk has been demonstrated for health or the environment.

SFT's assessment

Products containing lead which are included in the proposed regulation are not regulated in the EU. The EU Commission is of the opinion that the proposal will affect the market for many products and that the emissions from them are marginal. The measure is thus in their opinion not proportional. We have to a great extent built our proposal on the Danish prohibition. We are of the opinion that the Norwegian proposal will not affect the market in a manner other than how the Danish prohibition already does. Furthermore, the products we are proposing to regulate comprise a corresponding and comparable risk to what they do in Denmark. The EU Commission has already accepted these assessments in Denmark and that they have implemented a national prohibition.

The EU Commission's argumentation for the measure not being proportional is tied to the emission figures referred to in the impact assessment. They are pointing out that the products for which regulation has been proposed only comprise approx. 2 % of the total lead emissions. With respect to some products for which regulation is proposed, including paint, lacquer, glue, jewellery, imported musical instruments, fishing tackle and different plastic products (PVC) such as garden hoses, jerry cans, wallpaper, lunch boxes, electrical cables and electrical plugs, the emission figures are not accurate. These products do not contribute to direct emissions, but rather comprise a problem first and foremost when they become waste. As waste they have a potential for leaching into the environment if they are not looked after properly. Metallic lead has value as a resource for recycling whereas many consumer products containing lead do not have the same potential for recycling and will thus more easily fall outside the controlled waste streams. In addition, many of the

products concerned are building materials that have a long lifespan in a building and end up as demolition waste at a later point in time. Most of the consumer products that are encompassed by the proposal are not hazardous waste, but are included in the normal waste stream. With respect to fishing tackle, it is left in the sea and in bodies of fresh water.

EU Commission says correctly that the largest quantities of lead are found in metallic products that either are regulated or are exempted from the proposal. Nevertheless, the products that are encompassed by the proposal comprise approx. 120 tons of lead (where we are estimating that fishing tackle for consumers will comprise approx. 60 tons, which is approx. 25 % of the total quantity of fishing tackle) with respect to SFT's report on "Prioritised hazardous substances– Status in 2005 and emission prognoses". A total of 120 tons are a significant quantity of an undesirable substance and the trend is increasing for most of the products concerned. In addition, there are EE products that are not included in these figures and which make a substantial contribution.

Increased import of products, particularly PVC products from countries with no regulation of the area, will cause products to gradually comprise a more significant source of lead emissions in the Norwegian market as we beginning to gain control over the most significant sources at present. We thus are of the opinion that there is a basis for maintaining the proposal.

The primary objection against the proposal from the other consultative bodies is that the limit value is too strict and that the proposal encompasses the necessary presence of lead in, among other things, metals and alloys. We built our original proposal for regulation on Denmark's national regulation. They have established a revision to their regulation after we had sent our proposal out for consultation. We have studied their revised regulation and altered our proposal in line with the Danish regulation. This implies that the proposal regulating products that contain more than 0.01 % lead by weight and differentiating between metallic lead and chemical lead compounds. The proposal thus does not encompass application areas such as steel, tin, brass, aluminium alloys, copper and special types of glass. Through the consultative process, we have become aware that products that utilise recycled glass as a raw material will not be able to comply with the limit value of 0.01 % lead by weight. It is an objective to increase the recycling of waste and it is important to facilitate this where such is appropriate and possible. We are thus proposing a special limit of 0.05 % lead by weight for products made of recycled glass. In general, the areas that are regulated in the RoHS Directive are exempted from regulation of hazardous substances in consumer products.

SFT thus proposes to maintain the proposal to regulate lead in consumer products and to maintain the general limit of 0.01 % by weight, but to differentiate between metallic lead and chemical lead compounds. This general limit will regulate lead in jewellery corresponding to items in which lead has been demonstrated in Sweden. The proposal does not encompass application areas such as steel, tin, brass, aluminium alloys, copper and special types of glass. We are proposing a separate limit of 0.05 % lead by weight for products made of recycled glass.

DEHP

Consultative comments

A number of comments have been received saying that there is no basis for regulating DEHP beyond the existing regulation in toys and children's items. Among the reasons for this are that DEHP does not fulfil the PBT criteria, that the concentration of DEHP in the environment is diminishing and that the EU's risk assessment concludes that there is no risk to consumers except for children (toys and children's items) and materials coming into contact with food. In addition, risk-reducing measures are being assessed for medical equipment, production plants and workers. It was also pointed out that it is uncertain as to whether alternatives exist for DEHP as a softener in electrical cables. The EU is inviting Norwegian authorities to participate in the discussions concerning future EU regulation of plastics manufacturers.

SFT's assessment

The EU's risk assessment was completed in 2006. The substance has been classified as toxic for reproduction (Rep. Cat 2; R 60-61). Consultative statements from Japan have referred to results from primates. Such have also been taken into consideration in the EU risk assessment, however the conclusions are still that the substance may have effects that are toxic for reproduction, cf. the classification.

Because DEHP is classified as toxic for reproduction, the T criteria in the PBT criteria is thereby satisfied. However, the substance is not assessed by the PBT group to satisfy the P or B criteria, and DEHP is thus not deemed to be a PBT substance. The breakdown is however temperature-dependent and goes more slowly at low temperatures. DEHP has been monitored in freshwater, saltwater, wastewater, sediments, sludge, air (indoor and outdoor), organisms and foodstuffs such as meat, fish and milk. DEHP has also been found in human breast milk. Measurements in the Norwegian environment have however not been performed since 1996. It is important to note that production and use of DEHP in the EU and Norway have been significantly reduced in recent years (published at State of Environment Norway). Measurements have not been performed in the Norwegian environment in more recent years and it is unknown as to whether the restrictions that already have been implemented including voluntary substitution have led to a reduction in the Norwegian environment. DEHP is a prioritised substance in the Water Framework Directive. It is recommended that further measurements should be performed in the Norwegian environment and possible measures should be performed as a follow-up to the obligations under the Water Framework Directive.

The EU's risk assessment concludes that there is a risk to consumers in relation to tangible products such as toys and medical equipment. A possible risk of reproductive toxic effects to children has also been identified in consequence of exposure via intake of food and beverages that have been contaminated by DEHP in the vicinity of production plants or in the vicinity of municipal purification plants hence people who are exposed via the environment. In the RRS document (Risk Reduction Strategy) that has been adopted,

it was also pointed out that it is desirable to reduce the general background level for exposure of the general population.

Children and youths are the most vulnerable groups and they are already protected through existing regulation of toys and children's products in the Product Regulations. The EU Commission is now working with incorporating proposals for restrictions in the Limitations Directive or Annex XVII in REACH. The restriction the Commission is planning concerns a prohibition on the use of DEHP in different industrial processes if the emissions to the environment have not been sufficiently controlled. It is being proposed that a new assessment should be performed within a reasonable timeframe for restrictions on products that may be the source of emissions to water. There are also processes underway in the EU to expand the prohibition on phthalates to also include school materials.

We are proposing withdrawing DEHP from the proposal for a prohibition in consumer products and wait for the processes under the Water Framework Directive and further processes in the EU under the Limitations Directive and REACH. We are justifying this by the production and use of DEHP being significantly reduced in the EU and Norway and that in our opinion the most vulnerable groups have already been protected through existing regulation. Furthermore, DEHP is not deemed to be an environmental problem, however data from the Norwegian environment is out-dated and it is recommended that new measurements should be performed as a follow-up of the Water Framework Directive.

Hexabromocyclododecane (HBCDD)

Consultative comments

The EU Commission and others are asking Norway to wait for the process in the EU, where Sweden is working with a proposal for a risk reduction strategy. A number of replies have pointed out that the EU's risk assessment concludes that there is no risk to health and consumers and that we ought to wait for the conclusion from the EU as to whether HBCDD is a PBT substance. Canadian authorities state that they will probably conclude that HBCDD is toxic and that they have indications that the substance is persistent and bioaccumulating. A number of replies state that no alternative exists to HBCDD as a flame retardant in building insulation of polystyrene (EPS). Furthermore, electronic cabinets contain more HBCDD than the proposed limit value of 0.1 % by weight. Among others, this concerns HIPS, polycarbonate, rubber, epoxy resin and other polymers that can contain up to 75 % HBCDD. (The Swedish risk assessment says less than 7 %). Some individual replies point out that the proposal will lead to a prohibition on sales of consumer electronics in Norway.

SFT's assessment

HBCDD is extremely toxic to aquatic organisms, persistent and may cause long-term adverse effects in the environment. In the EU's working group for classification and labelling, no decisions have been made concerning health classification of HBCDD,

however a proposal does exist concerning classification with R64 "May cause harm to breast-fed babies". As early as June 2003, there was agreement that the substance should be classified as dangerous to the environment and labelled with N; R 50-53 with lower specific concentration limits down to 0.025 %. The classification has not been finally established because classification is being awaited with respect to health.

The EU's PBT working group has decided that HBCDD is a PBT substance (persistent, bioaccumulating and toxic). HBCDD is persistent and accumulates towards the top of the food chain (in top predators), even in remote areas. In addition, the substance is bioaccumulating and toxic.

The EU has presented a proposal for a risk reduction strategy. A proposal should be prepared to include HBCDD in the POPs Convention (the Stockholm Convention: the Convention on Persistent Organic Pollutants (POPs)) and that HBCDD should be included as a prioritised compound in Annex X in the Water Framework Directive (Directive 2000/60/EC). Further work with HBCDD is proposed to be continued under REACH. Experience indicates that it may be a long time before regulation of HBCDD will exist in the EU. The proposed regulations in EU involve consumer products to small extent and hence do not cover our primary objective of reducing emissions of HBCDD from consumer products.

Norwegian regulations concerning requirements for construction works and products for construction works and the EU's Construction Products Directive do not pose requirements for flame retardants in insulating materials, they only pose functional requirements. This means that requirements for fire safety may be fulfilled in another manner. In Norway, we have co-operated with the construction trade for a number of years on phasing out HBCDD where it is not strictly necessary. The consumption of brominated flame retardants by the construction business has thus been reduced significantly in Norway. No other flame retardants exist that can completely replace HBCDD in all areas, however there are other different brominated and bromine-free flame retardants that may be used in textiles, EE products and cellular rubber.

Our argument for RoHS Directive not being a harmonized directive, please refer to the section concerning arsenic, also applies for HBCDD. During the consultative process we have had Japanese standards submitted to us for electronics where several manufacturers are setting limits for HBCDD content. This means that the best companies are in a position to deliver products that fulfil our requirements.

In addition to the proposal for regulation of HBCDD in consumer products, SFT has also been commissioned by the Ministry of the Environment to assess a total prohibition on HBCDD. On the basis of a total assessment, SFT is of the opinion that it is most appropriate to continue to work for regulation of HBCDD in consumer products as described in a letter from SFT to the Ministry of the Environment dated 19 June 2008. It has not been demonstrated that any general regulation of HBCDD will have any environmental benefit to Norway or Europe in general beyond what we achieve with the regulation of HBCDD in consumer products. The estimated timeframe for

implementation of regulation of HBCDD in EU is uncertain. We are of the opinion that it is important to regulate HBCDD as soon as possible.

We thus propose maintaining the proposal to regulate consumer products with more than 0.1 % HBCDD by weight in the product's homogeneous individual parts. SFT is of the opinion that the proposal is justified and that the regulation such as it has been formulated satisfies the requirement for proportionality.

Cadmium

Consultative comments

A number of consultative bodies have commented that no alternative exists to cadmium in red and yellow glass for a number of purposes that include optical glass, architectural glass and artistic glass making. We have also been made aware that three specified inorganic cadmium compounds in artistic paints are specifically exempted from classification on the List of Dangerous Substances. Furthermore, it has been pointed out that the requirements in the Product Regulations are % weight, whereas the RoHS Directive poses requirements for % weight in homogeneous material. This has been changed in the most recent version of the Product Regulations.

SFT's assessment

SFT is proposing to maintain the proposal concerning regulating cadmium in consumer products. In light of the consultative comments, the three specified inorganic cadmium compounds in artistic paints that are exempted from classification on the substances list will be exempted from the proposal.

Furthermore, we are proposing that cadmium in red and yellow glass for special purposes should be exempted where no alternatives exist.

Medium-chain chlorinated paraffins (MCCP)

Consultative comments

The consultative bodies are asking the Norwegian authorities to wait for the process in the EU. TC NES (The EU's Technical Committee on New and Existing Substances) has concluded in its last meeting in May of 2007 that there is a need for further testing in relation to bioaccumulability. So far, it has been established that medium-chain chlorinated paraffins (MCCP) fulfil the criteria for persistence based upon read-across from short-chain chlorinated paraffins (SCCP).

SFT's assessment

Medium-chain chlorinated paraffins (MCCP) have been proposed to be classified as very toxic for aquatic organisms and may cause long-term adverse effects in the aquatic environment (R50/53). In addition, it is being proposed that they should be classified with the risk phrase "May cause harm to breast-fed babies," (R64) and "Repeated exposure

may cause skin dryness or cracking” (R66) (adopted by the EU, but waiting for evaluation at WTO).

The EU's PBT group has provisionally concluded that the substance satisfies the T (toxicity) and P (persistence) criteria. The P criteria is deemed to have been fulfilled based upon results from screening tests and ”read-across” from SCCP (short-chain chlorinated paraffins). A relatively high bioconcentration factor, BCF, of 1087 has been measured, but this is not sufficient to satisfy the criteria for B, which is greater than or equal to 2000. It is presumed however that intake via food can be an important factor for MCCP, something that may result in higher concentrations in organisms than what can be measured by BCF. Furthermore, it has been documented that some of the components in the technical mixture (mixture of components with chain lengths from C₁₄ to C₁₇) satisfy the B criteria.

The risk assessment/PBT evaluation concludes that there is a need for more data in order to determine whether the substance satisfies the B criteria in technical terms. Further testing of B (bioaccumulating) has been decided, but it is recognised that the results of the individual test in the proposed test programme may be difficult to interpret (RAR August 2007). In the draft for the risk assessment of August 2007, it was emphasized however that it could take a long time to acquire sufficient documentation in order to be able to draw reliable conclusions and it thus is recommended in the report that an assessment should be made to introduce regulations based upon the precautionary principle.

Measurements in the environment and biota can be vital to a final assessment of the substance's potential for bioaccumulation and concentration in the food chain. It was emphasized in the last draft of the risk assessment (August 2007) that MCCP has more recently been monitored in the environment using reliable methods and has been measured in human breast milk, cow's milk, some marine fish and marine mammals, even though the underlying data especially for fish and marine mammals is currently somewhat sparse.

Monitoring data (screening) shows substantial spreading in the environment in Norway, and this is an important basis for proposing regulation of MCCP. Both short-chain (SCCP) and medium-chain chlorinated paraffins (MCCP) have been measured at many places in Norway. The compounds have been demonstrated in blue mussels and cod livers along the Norwegian coast from Inner Oslo Fjord to Varanger Fjord and in fish from Drammen Fjord, Mjøsa and Øyeren. In fish, mostly SCCP has been found (something that indicates the larger bioaccumulation potential for SCCP), however in samples of fish from Øyeren MCCP dominated.

The substances have been measured in sediments in a number of harbours and marine stations along the coast. The highest level recorded in Norway was observed in sediments from Drammen Fjord, but the compounds have also been found in sediments in Mjøsa. In sediments, MCCP dominates. Both short-chain and medium-chain chlorinated paraffins have been found in run-off from waste disposal sites.

The EU Commission has prepared a proposal for regulation of MCCP, including metalworking and impregnation in the leather industry, in addition to MCCP being included on the prioritisation list Annex X to the Water Framework Directive. The proposed areas of use involve consumer products to hardly any extent and thus do not cover our primary objective of reducing emissions of MCCP from consumer products.

The reporter for the EU's risk assessment and individual member states are suggesting that precautionary principle measures ought to be evaluated. The EU has proposed that further work with MCCP should continue under REACH. The continuation of the process in the EU is uncertain and will take time. On the basis of a precautionary principle assessment, it is thus necessary to introduce national regulation while waiting for future EU regulation that covers all the relevant areas of use. Germany has the same perception as Norway that it is important to include, among other things, PVC products in any regulation of MCCP.

It is being proposed that consumer products should be regulated having more than 0.1 % MCCP by weight in the product's homogeneous individual parts. We are proposing to exempt products where there is a special need for flame resistance (fire safety) and no satisfactory alternatives exist, such may apply to, among other things, floor coverings and cables.

In relation to the body of regulations in the EEA Agreement and the WTO's body of regulations, regulation of MCCP in consumer products is deemed to be justified and entitled on the basis of the substance's health and environmentally hazardous properties in combination with the special risk the substance comprises to health and the environment when it is present in consumer products.

SFT has demonstrated that MCCP is present in many consumer products, particularly soft plastic and rubber products such as wallpapers, electrical wires and leisure time articles such as rucksacks, carrycots and camping chairs. Many of these products are produced in low-cost countries in Asia. Use of MCCP is inexpensive and is simple, and is in part an old technology. Regulation of MCCP is being proposed because the substance is on the Norwegian priority list, some of the individual compounds has PBT properties and have been found in the environment and demonstrated in the food chain, as well as in human breast milk. Satisfactory alternatives to MCCP as softeners exist and in individual areas as flame retardant. With continually increasing consumption and imports from Asia, the trend in consumption ought to be followed up on.

SFT is proposing to maintain the proposal concerning regulating MCCP in consumer products with more than 0.1 % MCCP by weight in the product's homogeneous individual parts. We are proposing an exemption for products where there is a special need for flame resistance (fire safety) and no satisfactory alternatives can be found. The proposal is justified by some of the components in the technical mixture of MCCP having PBT properties and that they are found widespread in the Norwegian environment. The reporter for the EU's risk assessment and individual member states are proposing that precautionary principle measures ought to be assessed. The process in the EU may take

time due to the transition to REACH. On the basis of a precautionary principle assessment it thus is necessary to introduce national regulation while waiting for future EU regulation.

Musk compounds

Consultative comments

We have received comments stating that the EU's risk assessments have concluded that there is no risk to health or the environment from musk ketone. For musk xylene the conclusion is that there is not any risk to health, but a need for more information concerning the environmental effects in relation to suspected PBT properties. There is agreement to provisionally deem musk xylene to fulfil the PBT criteria. Norway's proposal for regulation of musk ketone is deemed to be unreasonable, likewise for the proposal concerning musk xylene in relation to the risk to health. Norway ought to wait for more data concerning the risk to the environment for musk xylene.

SFT's assessment

Musk xylene and musk ketone (both are nitromusk compounds) have traditionally been treated equally in relationship to the Norwegian priority list and Norwegian assessments of needs for measures. OSPAR's "list of priority action" includes however "musk xylene", but OSPAR's background document also encompasses musk ketone and two other musk compounds. Risk assessments have been performed in the EU for both musk xylene and musk ketone and the substances have been evaluated by the EU's PBT group.

Musk ketone is assessed not to fulfil the PBT criteria (potentially P, but not B, T is borderline for environment). The risk assessment concludes that the present consumption does not entail risks.

SFT is proposing withdrawing musk ketone from the proposal for a prohibition on its use in consumer products since it has been clarified that the substance is not PBT, and more recent documentation in the risk assessment concludes that there is no risk.

Musk xylene is very toxic to aquatic organisms, bioaccumulating and persistent. Musk xylene is classified as carcinogenic in category 3 (Carc. cat. 3) with risk phrase R 40; "limited evidence of carcinogenic effect" and as dangerous to the environment with risk phrase R 50/53; "very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment". Musk xylene has been assessed to fulfil the vPvB criteria (very Persistent, very Bioaccumulating substance).

According to the EU's risk assessment, exposure to health and the environment occurs from consumer products by emissions from production and by the use of consumer products that contain musk xylene. Consumers may be exposed to musk xylene both by direct exposure from consumer products and by indirect exposure via the environment, for example through food. Musk xylene is stored in fat tissue and excreted in human breast milk, the level in human breast milk has diminished in the past decade. OSPAR

had recommended already in 2004 that measures for phasing out musk xylene should be assessed.

SFT is proposing to maintain the proposal to regulate musk xylene in consumer products. This is justified by the substance fulfilling the vPvB criteria and being classified as carcinogenic in category 3. Musk xylene is on OSPAR's list for priority action and OSPAR in 2004 issued a clear recommendation on assessing further measures for phasing out production and use.

Pentachlorophenol

Consultative comments

No comments

SFT's assessment

SFT is proposing maintaining the proposal on regulating pentachlorophenol in consumer products.

PFOA

Consultative comments

We have received a number of comments stating that Norway ought to wait for the process in the EU and the results of Germany's risk assessment, which will be completed in February of 2008. PFOA will also be dealt with under REACH. The textile industry has objections to the specific limit for textiles. They are of the opinion that the proposed limit has been set to a value 5000 times stricter than for consumer products in general and that it has not been shown that there is any basis for this. Nor has it been documented that it is possible to remove such low residual values from the textiles and hence it is not possible to conclude that there are no costs associated with such. They are of the opinion that exposure to PFO (the anion of PFOA) from consumer products is not damaging to health.

SFT's assessment

The EU risk assessment of PFOA is not nearly finished as the consultative comments might indicate. Germany is working with a draft for a risk assessment and it is uncertain when it will be available. The regulation of PFOA will continue under REACH and it thus is uncertain how long time of the process in EU will take. EU has recently classified PFOA as carcinogenic and harmful to reproduction (Carc Cat 3; R 40, Repr Cat 2; R 61).

SFT made a literature survey of PFOA in products in 2007 (PFOA in Norway, SFT, 2354/2007). It shows that PFOA is present in a number of products such as impregnated carpets, textiles, recreational and travel items, impregnated paper for food items (grease-proof) and impregnating agents, ski wax, paints and lacquers. The main conclusion of the survey is that the sources of the presence of PFOA are difficult to establish. A smaller

portion, approx. 14 kg, is deemed to come from products, essentially consumer products, which primarily have been imported into Norway. The primary source of emissions of PFOA, both from direct and indirect sources, is deemed to come from long-range transport, approximately up to 380 kg per year up to 2050. Consumption of products treated with PFO appears to be increasing in Norway, and hence no reduction may be expected in emissions via consumer products. The survey shows that it is primarily consumer products that contain PFOA. In order to avoid an increase in products with PFOA on the market, we believe that it is important to establish limits for the PFOA content in products.

We have received comments that the limit value for textiles is much too strict and coincide with low residual values of PFOA in the textiles. The limit value originally proposed of 1 ug/m² for PFOA in textiles will impact more textiles than the PFOS prohibition. A total of 10 of 11 textiles we have analysed contain more than 1ug/m² of PFOA. We are in agreement that the limit value for textiles is significantly stricter than the general limit value. A limit value for textiles that is based upon the quantity per square metre would have dissimilar effects for light and heavy textiles. The limit value for textiles and carpets thus ought to be differentiated. On the basis of information concerning average weight for textiles and carpets, we are proposing that we raise the limit value to 50 micrograms per square metre in textiles and other coated consumer products, for carpets we are proposing 500 micrograms per square metre. It will be possible for the best products to fulfil the requirements, whereas the products with the largest quantities will no longer be permitted.

SFT is proposing on the basis of the above to maintain the proposal to regulate PFOA in consumer products with a general limit value of 0.005 % by weight. We are proposing on the basis of the consultative statements and other relevant information to change the limit value for textiles to 50 micrograms per square metre in textiles and other coated consumer products and to 500 micrograms per square metre for carpets.

TBBPA

Consultative comments

Many consultative statements refer to the fact that the EU's risk assessment of TBBPA concludes that there are no risks to health or the consumer and controllable risks to the environment. The EU Commission states that the proposal is in violation of article 4.1 of the RoHS Directive if it encompasses electronics. Several comments state that the proposed limit value of 1 % by weight can be complied with for circuit boards however the content of unreacted/additive TBBPA in plastic may be up to 59 %. Furthermore, the regulations must differentiate between additive and reactive use. Canadian authorities say they will probably conclude that TBBPA is toxic and that they have indications of persistence.

SFT's assessment

It is correct as a number of the consultative statements point out that no risk has been demonstrated to health or the environment from TBBPA. The EU's provisional risk assessment of TBBPA states that no risk has been demonstrated to health from TBBPA. The substance is very toxic to aquatic organisms, not readily degradable and can cause long-term adverse effects in the aquatic environment. According to the EU's risk assessment, TBBPA fulfils the criteria for being able to be defined as very persistent (the vP criteria), but TBBPA is not a PBT or vPvB compound based upon current knowledge. The substance is deemed to not be concentrated in the food chain.

Under certain environmental conditions it is possible that TBBPA may be degraded into bisphenol A. This substance is dangerous to aquatic organisms because it has endocrine disrupting effects and bisphenol A also is dangerous to human health. The risk assessment for bisphenol A has not been completed in the EU because the results of a number of tests are being awaited, which may take a long time. The EU Commission has thus decided that the risk assessment of TBBPA with respect to the environment will not be concluded before the results from the risk assessment for bisphenol A are available.

The UK submitted a proposal for a risk reduction strategy (RRS) for TBBPA in October 2007. The draft for an RRS was adopted by the EU's working group and is ready for publishing. Regardless of the final conclusions in the risk assessment may TBBPA, there is agreement in the EU concerning risk-reducing measures for the scenarios for which risks have been identified. The relevant risk-reducing measures will be implemented in the IPPC Directive. Local emissions of TBBPA shall, where such is necessary, be controlled by national rules in order to ensure that there is no risk to the environment. The EU assessment concludes that at present there is no need for risk-reducing measures in relation to the health effects of TBBPA.

In addition to the proposal for regulation of TBBPA in consumer products, SFT has also been commissioned by the Ministry of the Environment to assess a total prohibition on TBBPA that is described in a letter from SFT to the Ministry of the Environment dated 19 June 2008.

In accordance with the conclusions in the EU's risk assessment and current knowledge about TBBPA, SFT is proposing waiting for the ongoing process in the EU both as regards the risk assessment and the proposal for including TBBPA in the RoHS Directive. Since TBBPA may be degraded to bisphenol A under certain environmental conditions there may also be need for a new assessment when the final risk assessment for TBBPA is available.

Tributyltin and triphenyltin compounds (TBT and TFT)

Consultative comments

The EU Commission has proposed a prohibition on certain organotin compounds, among them TBT and TFT, in consumer products. They are asking Norway to wait for the

process in the EU. The proposed limit value of 0.001 % by weight is 10 times lower than German data for risks with textiles that are in contact with the body and also require sophisticated analysis methods.

SFT's assessment

No risk assessments for TBT and TFT exist in the EU. TBT and TFT are classified as dangerous to the environment and are very toxic to aquatic organisms. The substances are also extremely toxic to warm-blooded animals. In addition, they can cause long-term adverse effects in the aquatic environment because they are persistent and accumulate in organisms. The substances thus fulfil the PBT criteria (persistent, bioaccumulating and toxic). TBT and TFT are classified as toxic to humans. TBT may cause serious damage to health by prolonged exposure.

The EU Commission has presented a proposal for a prohibition on certain organotin compounds in products, including TBT and TFT. The proposal for a directive includes consumer products in addition to other products, but the limit value is higher than our proposal. The EU is proposing 0.1 % tin by weight, whereas our proposal is 0.001 % TBT or TFT by weight. We cannot demonstrate that the EU's proposal for a higher limit value will have negative significance to the environment.

The proposal has been discussed in the EU's Limitation Working Group and will be addressed at its next meeting on 2 July. Since TBT compounds are already regulated in the EU, a further tightening of the body of regulations may occur via a comitology procedure, i.e. in a separate meeting or via voting by ballots, presumably during the course of the autumn. It has been suggested that a possible EU regulation will enter into force on 1 June 2009.

SFT is proposing to follow the EU's proposal for regulation of TBT and TFT in products. The EU's proposal encompasses more products than our proposal for regulation of consumer products. We cannot document that our proposal for a stricter limit value will provide better protection for the environment.

Triclosan

Consultative comments

Triclosan will be included in the Biocide Directive for a number of products, and SFT is being asked to wait for this process. Several comments refer to the fact that triclosan does not comprise a risk in the food area and hence in their opinion there is no basis for the proposal to protect vulnerable consumers. Furthermore, a part of our information in the impact assessment is rejected, among other things they are of the opinion that the quantity in 2005 is less than 1 ton, they are of the opinion that triclosan does not fulfil the vB criteria, nor does triclosan develop resistance to antibiotics with reference to the EU's Scientific Committee on Consumer Products (SCCP) and that triclosan is useful in toothpaste for many consumers.

SFT's assessment

The Biocide Directive only regulates triclosan used as a biocide in chemicals or in a production process within the EEA. The existing Biocide Directive will not encompass articles treated with triclosan imported from countries outside the EU.

The Biocide Directive encompasses only the marketing and use of biocide products in the EEA. This means that products that contain biocides (for example as a preservative), but which in themselves are not biocide products are not directly regulated. Such products produced outside the EEA and imported into the EEA will not be encompassed by any possible prohibition/limitations under this directive. Triclosan has been notified and is included in the assessment programme under the Biocide Directive. It has been listed under the product groups 1 (Biocide products for hygiene for humans), 2 (Disinfection agents for private use and use by the National Health Service and other biocide products), 3 (Biocide products for veterinary hygiene), 7 (Preservatives for film (for example paint film)) and 9 (Preservatives for fibres, leathers, rubber and polymerised materials).

If the application is sent in, the evaluation for these product groups will begin in 2007 and can be expected to be completed for all the relevant product groups in 2010-2012. It is not possible today to say anything about the outcome of this evaluation and whether the substance will be accepted for use as a biocide within some of the relevant application areas under the Biocide Directive. If the EU accepts the substance being used in biocide products it is unclear how such will affect a Norwegian regulation.

The proposal to regulate triclosan in consumer products involves to a large degree imported articles. It thus is important that regulation also include these products.

In the consultative statements reference is made to the fact that no risk has been demonstrated to health. The reference to the EU's Scientific Committee encompasses only health effects. The Dental Association has stated that they are of the opinion that it is unfortunate that toothpaste containing triclosan is sold to the general public. The proposal for regulation of hazardous substances in consumer products is primarily justified on the basis of the need to protect the environment and the consumers via the environment.

Norwegian environmental authorities have previously received support in the EU for having triclosan classified as dangerous to the environment. The Norwegian Scientific Committee for Food Safety (Norwegian Initials: VKM) concluded in its risk assessment of triclosan that its use thus ought to also be restricted from an ecotoxicological point of view. Triclosan fulfils the toxicity and bioaccumulation criteria. Since the widespread occurrence of triclosan has been demonstrated in the environment, including in sediments, indications are that the substance is not readily degradable. This data and the possibility for resistance to antibiotics to develop in bacteria dictate that triclosan ought to be regulated.

The Norwegian Scientific Committee for Food Safety has documented previously that applicable regulation in the EEA body of regulations for cosmetics is not sufficiently strict on the basis of toxicological risk assessments. Norwegian healthcare authorities

have on this basis also been the driving force (including participation in working groups in the EU) for work on further clarifications within the EU.

SFT was commissioned in 2007 to evaluate fees for products containing triclosan. SFT wrote in this regard in the letter to the Ministry of the Environment that we recommend regulation as the best means and if such is not possible, then a fee should be evaluated.

SFT thus proposes maintaining the proposal on regulating triclosan in consumer products.

Selected surfactants – DODMAC, DHTDMAC, DTDMAC

Consultative comments

A number of consultative bodies have commented that the EU's risk assessment of DODMAC (DSDMAC) has concluded that there is no risk to health and the environment. DODMAC is the primary component in DHTDMAC. Questions are being posed as to whether DTDMAC, for which no risk assessment has been performed, represents any risk to the environment. Without further documentation, the Norwegian proposal is not justifiable.

SFT's assessment

DODMAC is not produced as an isolated substance, but is rather included as a primary component (42%) in DHTDMAC and DTDMAC. Neither DODMAC nor DHTDMAC are readily degradable. DODMAC is classified as Xi R41 and N R50/53. In the IUCLID database, all three of the compounds are designated as synonyms.

A risk assessment has been performed in the EU for DODMAC in 2002 with conclusion (ii) for all points. That is to say that there is neither risk nor any need for more investigations, however this was justified by low consumption. It is noted that a risk assessment for DHTDMAC (used as a fabric softener) based upon consumption figures in 1989/90 gave rise to risk to the environment (aquatic organisms and sediment). The risk assessment concludes that the present consumption does not entail risks. It is noted thus that it must be ensured that the use of DHTDMAC does not increase in the future.

In the Detergent Regulation, DTDMAC is mentioned in particular as a prioritised substance that ought to be restricted. Surfactants in detergents must show ultimate degradation, otherwise they are prohibited. (The regulation regulates the content of surfactants in washing and cleaning agents with a cleansing effect, including fabric softeners. Exemptions may be applied for, and in such case requirements are posed for risk assessments.)

The major quantity of the selected surfactants is found in products regulated by the Detergent Regulation and there is only a small quantity of products remaining on the Norwegian market that may contain the surfactants mentioned. Since the risk assessment also concludes that there is no risk or need for additional investigations, provided that

consumption is kept at a low level, we hence are assessing that there is no need for expanded regulation now of the selected surfactants in consumer products.

SFT is proposing on the basis of the above to withdraw the proposal to prohibit the three surfactants mentioned in consumer products because the risk assessment concludes that there is no risk based upon current consumption.

SFT's assessment of follow-ups on definitions, purpose provisions, scope, exemptions, transition time etc.

Some general consultative statements have been received with comments of various natures. Some of these comments in definitions, purpose provisions, scope, exemptions and transition time are addressed below. Many have taken a critical view of the proposal and are posing questions as to whether Norway has the facility to introduce a national prohibition on the proposed substances. They refer to the EEA Agreement and the WTO regulations and refer in particular to the principles concerning justification, proportionality and non-discrimination. With respect to a meeting with the Ministry of the Environment on 28 September 2007, these questions of principle are being evaluated by the Ministry, and are not encompassed by SFT's technical assessments in this document. A summary of the general consultative statements is given in appendix 2 and the impact statements in appendix 4.

Purpose provisions

Consultative comments

It has been pointed out that the purpose paragraph in the proposal is worded differently than in the Product Regulations and we have also received comments on the use of the concept of "environmental toxins".

SFT's assessment

In the proposal for the prohibition we have used the concept "limit" instead of "prevent" such as it appears in the Norwegian Product Control Act and we have used the term "environmental effects" instead of disturbance of the environment such as is done in the Product Control Act. We are proposing using the same concepts as in the purpose paragraph of the Product Control Act in order to ensure uniform use of the concepts. *We are thus proposing that these concepts be changed in line with the Product Control Act.*

We have also received statements to the effect that we have used the phrase priority hazardous substances. After processing the consultative statements, a number of substances have been withdrawn from the proposal. All of the substances that are maintained in the proposal fulfil the criteria for prioritised substances and are thus to be

regarded as priority hazardous substances. *We are thus proposing that the term hazardous substances be maintained in the regulations.*

Definition of consumer product

Consultative comments

A number of consultative bodies have commented that the definition of consumer product is unclear and that the definition of the products' homogeneous parts ought to be described more clearly.

SFT's assessment

The definition of consumer product is in line with the definition in the Product Control Act. We are of the opinion that it is important that these two definitions are identical in order to ensure the uniform use of concepts and *thus we propose maintaining the definition of consumer product.*

We have applied the same definition of the products' homogeneous parts as in the RoHS Directive however this does not emerge clearly from the proposal. This hence should be made clearer when the regulations are established.

Scope/Exemptions

Consultative comments

The proposal mentions exemptions for coal and ore and ore concentrates. We have received statements with questions concerning why we are excepting coal and ore and ore concentrates specifically when such are not regarded as consumer products.

SFT's assessment

We propose that this exemption in the last subsection of section 4 should be removed from the proposal.

Transition time

Consultative comments

We have received statements in which the need for transition time is pointed out.

SFT's assessment

In the letter accompanying the request for consultative comments it was stated that we were intending for the prohibition to enter into force 1 January 2008. The comments submitted have been given in light of this. Assessments of a need for a transition period ought to be made at a later point in time when it is clear precisely which substances will be regulated and when the regulation will possibly enter into force.

The precautionary principle

Consultative comments

Many comments have been received on the justification of the use of the precautionary principle.

We have received support from a number of comments that are of the opinion that the proposal is in line with the EU policy on "the precautionary principle", and that it is necessary when it concerns specific health and environmentally hazardous chemicals that may conceivably comprise a special risk to both humans and the environment.

Other consultative bodies have commented that the criteria for the use of the precautionary principle have not been fulfilled, primarily because the impact assessments are deficient and that no risk assessments have been performed for specific products. They are thus of the opinion that the proposed measures are not proportional with the effect that is being sought to be attained. Hence the precautionary principle cannot be applied. Reference is made, among other things, to the Kelloggs case, with the opinion that SFT is not following the criteria that were drawn up there. Individual comments refer to the fact that the Commission emphasizes that use of the precautionary principle must only be temporary. Regard has not been paid to this in the proposal and use of the precautionary principle is not justified.

It is pointed out, furthermore, that SFT has not evaluated the proposal with relation to the EU's comprehensive guidelines for use of "the precautionary principle". Reference is made to the fact that for those of the substances for which a risk assessment has been completed in the EU with the conclusion that there is no need for further information or risk-reducing measures, then the uncertainty must be said to be negligible. Nor is it possible then to see that the prerequisite in the guidelines of the Norwegian Government Agency for Financial Management have been fulfilled (criteria 1). For substances that are close to completion of a risk assessment, SFT ought to justify why there is no time to wait for the process and obtain more information (criteria 4).

For a number of substances, reference is made to a more general precautionary approach. This is generally permitted for measures justified by a precautionary approach under the relevant agreements where the activity obligation especially in the short run is central with respect to obtaining relevant scientific studies. Even though a "precautionary approach" is not regulated in the same manner in the other agreements, it ought to be taken into account that there is a certain activity obligation when the measure must also be justified in other agreements.

SFT's assessment

The EU Commission has prepared a document concerning the use of the precautionary principle "Communication from the Commission on the precautionary principle, COM (2000) 1 final". They establish that the precautionary principle primarily concerns the

health of future generations and an assessment of the potential risk over a longer period of time.

The document also establishes that regard must be paid to the precautionary principle within WTO agreements such as the TBT Agreement (Technical Barriers to Trade). This means that the member states of the WTO have an independent right to determine precisely what level of national protection for health and the environment they deem to be appropriate. The member states of the WTO may introduce measures that result in greater protection than the international standards and recommendations involve.

The substances for which regulation is being proposed in this context are prioritised hazardous substances and thus among the most dangerous we are aware of. The effects of these types of substances are quite serious in that they are persistent, bioaccumulating and/or toxic, for example harmful to reproduction. These effects have to be regarded as irreversible. Hazardous substances accumulate in nature and in the food we eat. Hazardous substances are a serious threat to the health of future generations, to the environment and to future food safety. Many of the proposed substances have properties that make it too late to intervene with measures once the damage has arisen. On the basis of the documentation we have concerning health and environmental effects, data on occurrences in Norway and the potential danger of risks to long-term effects, we are of the opinion that there is a basis for establishing regulations that limit the sources and reduce the emissions of the selected hazardous substances. Monitoring data from Norway, in particular data from newer screening studies shows a substantial spreading of the substances in the environment today.

Products are an important source of emissions. Consumer products are especially important because consumers lack the requisite knowledge of the health and environmental problems connected with the use and disposal as waste of these substances. They have neither the requisite knowledge nor the possibility to protect themselves against the emissions. The entire population, including vulnerable groups such as children, will thus be exposed to emissions from consumer products, either directly or indirectly via the environment. Reducing the quantity of substances hazardous to health and the environment contained in product is also an important measure in reducing the quantity of hazardous waste that arises. Consumer products are an important source of the uncontrolled diffusion of hazardous substances in the environment.

When there is a need to limit problems associated with many and extremely different products, it is easier and more efficient to regulate as near to the source as possible and as early as possible in the supply chain. It is very difficult to intervene with measures that effectively hinder the uncontrolled diffusion of hazardous substances at a later point in time once the products have been spread throughout the market. We are thus of the opinion that the proposal to regulate certain hazardous substances in consumer products fulfils the general principles for risk management.

The health and environmental effects of the substances for which regulation is being proposed will only first be able to appear in many years. It thus is crucial to limit the risk

connected with the use of products with such hazardous substances. In particular because the monitoring data shows that the substances are found in the Norwegian environment. In order to achieve a limitation of the risks, we are of the opinion that it is necessary to regulate consumer products that contain more than the proposed limit values for the selected hazardous substances. Products that contain less than these limit values will be legal to sell. We have taken into account comments from the consultative process in establishing limit values. A number of the originally proposed limit values have been raised to a realistic level that is possible to comply with, while at the same time achieving the desired protection. Furthermore, we have exempted a number of application areas where at present no good alternatives exist. The proposal is thus proportional in relation to the results that we wish to achieve.

The proposal treats all consumer products equally. It encompasses both imported products as well as products produced in Norway and thus is non-discriminatory.

Regulation of hazardous substances in consumer products has been based on the same principle as is usual for regulating hazardous substances and products in the Limitations Directive and the Norwegian Product Regulations. The proposal for regulation of hazardous substances in consumer products is thus in accordance with other bodies of regulation in the product area.