

Impact assessments of proposals for regulation of certain hazardous substances in consumer products

Scope of the regulations

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. Hence it is extremely important to limit emissions of them. Products are an important source of emissions of hazardous substances. The substances for which regulation is being proposed are prioritised hazardous substances and thus among the most dangerous we are aware of. Consumer products are especially important because consumers lack the requisite knowledge of the health and environmental problems connected with the use and disposal of these substances. Nor do they have the requisite knowledge and equipment to be able to protect themselves against the emissions. The entire population, including vulnerable groups such as children, will thus be vulnerable to exposure from emissions from consumer products, either directly or indirectly via the environment.

It thus is proposed that defined hazardous substances in consumer products should be regulated when the content of the substance in the product's homogeneous individual parts is greater than or equal to a specified limit value. The regulation concerns arsenic, bisphenol A, lead, hexabromocyclododecane (HBCDD), cadmium, medium-chain chlorinated paraffins (MCCP), musk xylene, pentachlorophenol (PCP), PFOA and related compounds and triclosan.

The proposal for regulation of certain hazardous substances in consumer products will become a part of the Norwegian Product Regulations, as a new chapter of such. The demarcation line towards other regulations will thus be the same as for the Product Regulations in general. We have nevertheless found it necessary to specifically exempt certain consumer products from the chapter's scope due to informational considerations in those cases where the delimitation to other bodies of regulations may be somewhat unclear, as well as for certain consumer products for which it is not the intention that they should have to be encompassed by the regulations. SFT is proposing exempting foodstuffs, food product packaging, fertiliser, tobacco and medicaments from the scope. We are proposing, furthermore, that means of transport, permanently mounted equipment for means of transport, tyres and similar accessories for means of transport should be exempted specifically from the scope of the regulations because the substances in these products are not regulated in other bodies of regulations, and that the use of some individual substances that are encompassed by the regulations is necessary in these types of products on the basis of security-related considerations. Nor do the regulations apply for substances and products that have already been regulated through harmonised EEA bodies of regulation (implemented in the Product Regulations), such as certain substances in electrical and electronic products that are regulated

in the ROHS directive. In addition, a number of products will be exempted from regulation in the individual paragraphs.

For cosmetics, exemptions will be made initially from the regulations for some substances that have been regulated in the Norwegian Cosmetics Regulations, more specifically arsenic, lead, cadmium, bisphenol A, musk xylene, pentachlorophenol and triclosan. These substances are currently regulated in the Cosmetics Regulations on the basis of health considerations. The environmental authorities will assess at a later point in time whether there is a need and possibility for still stricter regulation of these substances in cosmetics due to regard for the environment.

Because cases of doubt may arise concerning whether a product is encompassed by the proposal for regulation of certain hazardous substances in consumer products, it is proposed to insert in section 2 last subsection of the proposal that SFT or a body authorised by the Ministry of the Environment decide in cases of doubt whether consumer products are encompassed by the scope of the chapter.

For most of these substances, we expect that the costs associated with the proposal will be relatively limited. This includes cadmium, musk xylene, triclosan and pentachlorophenol. The combination of limited costs and serious effects of emissions involve that we on the basis of available information expect that the benefit associated with the proposed regulation of these substances will be greater than the costs.

For the remaining substances, arsenic, hexabromocyclododecane (HBCDD), medium-chain chlorinated paraffins (MCCP), bisphenol A, lead and perfluorooctanic acid (PFOA), the proposal could entail costs however we expect such not to be significant. Information concerning quantities of emissions and the spreading and possible harmful effects are however uncertain, and valuation estimates of the harmful effects are lacking. We are of the opinion, regardless, that on the basis of our documentation the benefit is greater than the costs.

For those substances for which regulation is being proposed, simple impact statements have been made that are summarised in separate forms, one for each substance.

As appears from the impact statements, the effects of these types of substances are very serious in that they are not ready degradable, bioaccumulative and/or toxic, for example harmful to reproduction. These are conditions that cause the effects to be regarded as irreversible. Monitoring data from Norway, in particular data from more recent screening studies shows a substantial spread of the substances in the environment. To acquire sufficiently reliable knowledge of the long-term effects of these substances would take an extremely long time, and viewed on the basis of the serious consequences we do not view such as a relevant solution. Regulation thus in our perception ought to be implemented as quickly as possible on the basis of the existing information for all the proposed substances.

Description of risks to health and the environment

The relevant substances are hazardous substances. Hazardous substances are substances that represent an especially serious problem in relation to health and the environment. These substances have one or more of the following properties:

- are not ready degradable and accumulate in living organisms and have serious long-term effects on health, or are extremely toxic in the environment
- are persistent and accumulate extremely easily in living organisms
- are found in the food chain at levels that give grounds for concern or
- equivalent reasons for concern, such as endocrine-disrupting substances and heavy metals.

Norwegian monitoring data shows occurrences of the hazardous substances in the proposal in the Norwegian environment. We find substantial spreading and for some substances in part high values for, among other things, bisphenol A, HBCDD, MCCP, PFOA and triclosan.

Hazardous substances in consumer products are being spread in very many different types of products. In contrast to occupational users, consumers often do not have sufficient knowledge of safe use of the products, access to protective equipment or knowledge of safe disposition of waste. This involves exposure for the users, either directly or indirectly via the environment, for example due to emissions to the environment throughout the lifespan of the product, or because the residual products to a large degree end up in normal household waste. Consumer products cover a large range of products, such as shoes, clothing, toys, suitcases, rucksacks, wallpaper, floor covering, building insulation, TVs, PCs and mobile telephones. Monitoring data confirms that hazardous substances that end up in land fills will gradually leach out. Because they are not ready degradable and accumulate in living organisms, a long time can pass before the damage is detected. At this point in time it will be impossible or so difficult and so expensive to alleviate or repair the damage that such damage must be regarded as being irreversible. Hence it is important to put a special emphasize on consumer products now.

Current policies

Norway has adopted the goal that hazardous substances with serious long-term impact on health, or are highly toxic for the environment, must be reduced significantly in the short run and their use and emissions stopped completely within 2020, the so-called generation target as described in Storting White Paper No. 14 (2006-2007) "Working together towards a non-toxic environment and a safer future". The hazardous substances in the proposal are all substances that are given high priority in this report. As the first step along the road achieving this goal in 2020, another goal has been set earlier to halt or significantly reduce the emissions of prioritised hazardous substances at the latest before 2010. The list of the prioritised hazardous substances is often referred to as the government's priority list. SFT prepares a report annually on national emissions of the prioritised hazardous substances. The contribution of the products to emissions of hazardous substances has increased in recent years in comparison with the traditional emission sources such as industry where the emissions have been reduced somewhat significantly in recent years. A reduction in the emissions from products is crucial in achieving Norway's objectives in the area. Consumer products comprise a significant part of these products.

It is important to protect consumers against consumer products that have a direct effect on their health. However, it is also important to regulate products where consumers are important contributors to the spreading and effects of hazardous substances on the environment. Consumer products cause the comprehensive and nearly uncontrollable spread and exposure of many prioritised hazardous substances to the environment during their use and when they become waste. Most consumer products end in household waste that is not intended for managing hazardous substances. The lifespan of electronic products is relatively short, and

replacements and new acquisitions are substantial. Continued growth is expected in this market. For some products, separate return systems exist, for example for EE products. Even with these return systems it is difficult to collect all small electronic devices such as mobile telephones, economy light bulbs and toys with inbuilt electronics. Norway has a good system for collecting and processing EE waste, and in 2007 a total of approx. 148,000 tons was collected. A total of 54 % of this was estimated to have originated in the households. The degree of collection of large products, such as washing machines and TVs for example, is high. Investigations show however (Norstat/SFT 2007 – 1000 respondents) that the degree of collection for small electronics such as mobile telephones, electronic toys and other products, still is low. Around approx. 60 % of those who were asked answered that they had not delivered products such as mobile telephones and electronic toys to the return companies. This means that large quantities of small electronics that are discarding are going astray, and there is no control over the hazardous substances in these products. Many consumer products in fact end up as hazardous waste today. By regulating these products it will be possible to reduce the quantity of hazardous waste that arises from consumer products.

Evaluation of means

It is important that there will be a significant reduction of the emissions quickly. This is a broad spectrum of very different undesirable products with substantial spreading which it is important to stop before they are put on the market. SFT is thus of the opinion that restrictions (regulation) on the use of the specified hazardous substances in consumer products would be the best means because it gives the best control efficiency. Use of financial means would be less relevant because the aim is to reduce the emissions substantially in the short run. Financial means generally give less control efficiency than regulations. A fee system that would encompass so many different substances in so many different products, both as chemicals and as content in imported manufactured products, would be extremely complicated to design and particularly to enforce. Furthermore, the fee would have to be extremely high in order to have an effect.

The importance of acting precautionary

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". In it, they establish that the precautionary principle primarily concerns the health of future generations and the assessment of potential risks over a longer perspective in time.

The document also firmly 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 EU Commission writes in the document that there is a basis for applying the precautionary principle when the documentation is deficient (insufficient), uncertain, makes no conclusion and when there are indications of possible harmful effects on people or the environment that are not in accordance with the existing level of protection. Relevant scientific data must be evaluated. It is not possible in all cases to perform a complete risk

assessment, but attempts must be made to assess the available scientific documentation. Even if the scientific documentation is only supported by a minority within the scientific community, their viewpoints must be taken into consideration if they are credible.

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 are conditions that cause the effects 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 Norwegian environment and the potential danger of risks for 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 disposition 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 vulnerable to exposure from emissions from consumer products, either directly or indirectly via the environment. To reduce the quantity of substances hazardous to health and the environment in products, it is also an important step to reduce the quantity of hazardous waste that arises. Consumer products are an important source of the uncontrolled spreading of hazardous substances in the environment.

When assessing introducing measures on the basis of the precautionary principle, such must be set up against the risk associated with not doing anything. What the most relevant measures are can always be discussed. 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 spreading 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 be seen 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 present in the Norwegian environment. In order to achieve a limitation of 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 lawful to sell. We have taken into account comments from the consultative process in establishing limit values, with a number of the originally proposed limit values having 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 alternatives are available that are good enough. 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 built up in a manner corresponding to what 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.

Cost-benefit assessments for all the hazardous substances in the proposal follow in this document. The impact assessments build on the documentation that it has been possible to acquire for the different substances within the specified deadline.

We are aware that there is a large degree of uncertainty connected with a number of aspects of the proposed regulations. We are however of the perception that the measure, on the basis of the precautionary principle, ought to be carried out even though we do not have completely satisfactory information on the substances concerned and the costs the regulation would involve for the stakeholders. In the guidelines of the Norwegian Government Agency for Financial Management for handling uncertainty in economic analyses, four criteria are posed for when the precautionary principle may be used. These are:

1. Large and unquantifiable uncertainty connected with future consequences
2. The damages can be dramatic
3. The damages may be irreversible
4. There is no time to wait for developments and acquire more information

For all the substances the uncertainty is large and it is impossible to quantify, among other things, the health and environmental damage using the currently available knowledge. Experience indicates that extremely unfortunate effects are often revealed due to these types of substances over time. There thus are good reasons to believe that such will also be the case with these substances. As it emerges from the foregoing, the effects of these substances are very serious in that they are persistent and bioaccumulating. This is a condition that makes them in practice to be regarded as irreversible. Acquiring sufficiently reliable knowledge about the long-term effects of these substances would take an extremely long time. Viewed with the background of the dramatic consequences these substances have, we do not deem it to be a relevant solution. The substances concerned thus fulfil in our opinion all these criteria and the regulation hence in our opinion ought to be implemented as soon as possible on the basis of the existing information.

Basis for the evaluations

The proposal for regulation of selected hazardous substances in consumer products encompasses an assessment of many substances with many application areas. It is extremely complicated to acquire information on the content of substances in the very substantial number of products that are on the market in Norway. The Product Register contains information concerning chemical substances and products (substance mixtures). This register does not however contain information on the content of substances in manufactured products.

In addition, it is extremely complicated to estimate emission quantities from these products, their spread in the environment and to estimate precisely what health and environmental damages will arise in consequence of such. We are lacking a valuation basis for such damages for most of these substances. We have primarily based the assessments on what is available in existing reports, both as regards application areas, consumption quantities, occurrences in products (including our own analyses), occurrences in the environment and the consequences. During the work with the proposal we have had contact with different industry organisations, and we have also assessed and taken into consideration comments that have come from the consultative round.

In relation to the body of regulations in the EEA Agreement and the WTO's body of regulations, the measure is deemed to be justified on the basis of the special properties hazardous to health and the environment of the chemical substances in combination with the special risk such substances comprise for health and the environment when they occur in consumer products.

In our assessment, there are no specific legal regulations/total harmonisation requirements in the EEA body of regulations for chemicals that pose an impediment to the proposed regulation. We have evaluated regulation in relation to the EEA Agreement for each individual substance and are proposing exemptions from the regulation where we are of the opinion that the application area of the individual substance is regulated through a totally harmonised EEA body of regulations.

Cost estimates

The evaluations of the consequences associated with the proposed regulations are mainly a general description of application areas, health and environmental properties and possible alternatives. With respect to the expenses for the industry associated with the proposed regulation, we know that in most of the application areas alternative products exist on the market that satisfies the proposed requirements. We are not familiar with all these alternatives in detail, and do not have cost estimates for such. In those cases where we know that commercially available alternatives exist, we have roughly made it a precondition that a limitation will not entail costs of significance.

The proposed regulations are not a total prohibition, but are based upon limit values for content of the individual substance in homogeneous parts of the products. This means that the products may contain small quantities of the relevant substances. How large of a quantity will be permitted varies from substance to substance. This adaptation has been made in order to simplify the implementation and thus reduce the costs for the industry. For many application areas, we have proposed that exemptions should be given. This is due primarily to some application areas already being strictly regulated, including with respect to the EEA Agreement, a lack of satisfactory alternatives, a small effect on health and the environment by including the application area or that regulation of this application area must be expected to give rise to significant costs.

During the consultative process and notification in the EU and WTO, many comments have been received, particularly concerning limit values and the need for exemptions. In the setting of the limit values, regard has been paid to a large extent to these comments. A number of the limit values in the proposal for regulation are with respect to existing international standards that large international companies set for their subcontractors. We thus know that the best

companies are able to deliver parts and products in accordance with these requirements. Furthermore, we have also made exemptions where no satisfactory alternatives exist. These exemptions build to a large degree on the consultative statements.

In the formulation of the proposal an emphasis has thus been made on reducing the costs as much as possible without impacting the environmental effectiveness of the proposal to too large of an extent. We are of the opinion that the proposal balances this relationship such that it is technically possible to fulfil the requirements, while simultaneously making it no longer legal to sell the products of most concern regarding human health and the environment. We are thus of the opinion that the benefit of the measure may be expected to be greater than its costs.

Continued work – need for further information

During the work on the formulation of the proposal for regulation, we have had extensive industry contact and arranged three open industry meetings in order to crosscheck our proposal with them. Further application areas have emerged during the consultative process. Together, this gives us a comprehensive overview of the most important and the majority of the application areas for all the substances. We cannot however ignore the fact that there are special application areas that we are unaware of. Such may be due to the importers not being aware that their products contain the substances concerned.

The impact assessments build on the documentation concerning the properties hazardous to health and the environment and the potential risk of the substances that were available at the point in time concerned. The decisions concerning regulation were made on the basis of such. If new and significant information should emerge concerning risks, alternatives, costs or other significant information concerning individual substances that are encompassed by the regulations or have been omitted on the basis of consultative statements, the substances will be taken up for a new assessment.

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

Arsenic and arsenic compounds

1) Substance or substance group

Arsenic and arsenic compounds

2) Known application areas

Metallic arsenic:

- Brass
- Ammunition

Chemical arsenic compounds:

- Glass items (window glass, crystal glass, lead glass)
- Glass beads for road marking paint (not a consumer product)
- Plastic/PVC products (including garden articles, travel-/recreational articles, building materials and wallpaper)
- Lead storage batteries
- Joint sealant
- Textiles
- Mineral fertiliser
- Antifouling substances
- Cosmetics
- Previously in pesticides, including wood impregnation
- Electrical and electronic products (EE products) (including circuit boards, semiconductors, LED lamps)
- Tobacco

Previously, arsenic occurred in lead shot, pesticides and wood impregnation. The use of lead shot is now prohibited in Norway. Arsenic occurs in electric and electronic products, and may also occur in other imported products, particularly products based upon recycled materials such as glass and plastic. Also appears as impurities in other products, particularly those with lead content.

Registered quantities in Norway (2005) (arrow up/down: Trend in consumption from 2004) (ref. SFT report TA 2296/2007 - Hazardous substances in products - data for 2005).

- Wood impregnation 2.9t ↓ (not incl. import)
- Brass 29t ↓
- Lead storage batteries 12t ↓
- Ammunition 2.3t ↓
- Glass items 0 (not incl. import)
- Road markings 0.9t
- Pesticides 0
- Mineral fertiliser 0.79 t ↑

The list also contains application areas/products that are only for occupational use, and these will not be encompassed by regulation of arsenic and arsenic compounds in consumer products.

The quantity of arsenic compounds in EE products has not been registered. Arsenic and arsenic compounds are utilised in components in most EE products, including as a substrate in semiconductors and as flame retardants. Consumer electronics is a diverse and large market in Norway, with a turnover of approx. NOK 31 billion in 2007, i.e. many millions of units per year. Just in 2007, for example, a total of 2.3 million new mobile telephones were sold in Norway.

The quantity of arsenic in products sold in 2005 (ref. www.miljostatus.no, SFT report TA 2296/2007 - Hazardous substances in products - data for 2005): approx. 48 tons. Information has been taken from the Product Register, customs statistics and from manufacturers and importers. The quantity of arsenic in EE

products is not included in these figures, and thus nor are potential emissions from such products.

3) Description of risk to health and the environment

Arsenic and arsenic compounds: Not degradable and may be acutely and chronically toxic for many organisms, even in small concentrations. They are very toxic for aquatic organisms, and may cause undesirable long-term effects in the aquatic environment. Some compounds are carcinogenic. This substance satisfies all the criteria for the use of the precautionary principle as mentioned in the introduction.

Arsenic has been shown in the air, reindeer, sediments and soil contamination. The emissions of arsenic were limited to 29 tons in 2005, and have been reduced by approx. 18 % from 1995 up through today. Of this, emissions from the standing mass of CCA-impregnated wood are computed as 22 tons. Emissions from other products, including emissions from municipal drainage are computed to be 4.5 tons. The quantity of arsenic in EE products has not been registered, and emissions from this product group are thus not included in these figures. In addition, there are emissions from contaminated soil that are computed to be 6 t, and emissions from industry and transport. Emissions from the standing mass and contaminated soil will not be affected by regulation of the use of arsenic in products.

4) Occupational use

- Mineral fertiliser
- Wood impregnation with CCA
- Glass beads for road marking paint

Application areas that are only for occupational use will not be discussed further in this overview.

5) Consumer products where arsenic is already regulated today or where assessments/processes are occurring internationally

Here, only the body of regulations that deals with products within the scope of the proposal will be mentioned.

- Cosmetics: The Cosmetics Regulation, appendix IIA: Prohibited. Trace quantities permitted: In cosmetics 5 mg/kg. In toothpaste 0.5 mg/kg (established by the Ministry of Social Affairs and Health Services, now the Ministry of Health and Care Services).
- Antifouling substances and wood preservatives: The Product Regulations, section 2-7 and section 3-6, regulate arsenic and arsenic compounds in antifouling substances and for wood preservation (established by the Ministry of the Environment).

On-going processes/assessments internationally:

The Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment 2002/95/EC (RoHS) is under revision. 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 conclude them, and that it hence will take a long time before new substances are possibly included in RoHS.

6) Alternatives

By swapping out materials containing lead (for example lead in plastic and glass) arsenic will also disappear because it occurs as an impurity in these materials.

In Europe, a production method is used for glass in which arsenic cannot be used for technical reasons (float glass). In China, a production method is used in which arsenic is a part of the process (broad glass). There are commercially available alternatives without arsenic and lead.

Arsenic is used in semiconductor production, and at present there are no alternatives that have corresponding good and necessary properties, particularly when it concerns the use of integrated circuits such as microprocessors and memory chips.

Large electronics manufacturers utilise standards for deliveries for their products in which limit values have been set for the content of different chemical substances. Exemptions are also granted for the use of the substances for certain application areas where no satisfactory alternatives exist today. Requirements are then posed for the content of the substances to have to be documented.

7) Proposal for further regulation

It is being proposed that consumer products with a content of arsenic and arsenic compounds shall be regulated in the following manner:

It is forbidden to produce, import, export and sell consumer products that contain arsenic or arsenic compounds when the content of the substance in the product's homogeneous individual parts is greater than or equal to 0.01 percent by weight.

The prohibition in the first subsection does not apply for:

- tobacco,
- lead storage batteries,
- brass,
- crystal glass,
- lead glass,
- antifouling substances and wood preservatives that are regulated in section 2-7 of the Product Regulations,
- arsenic-treated wood that is regulated in section 3-6 of the Product Regulations,
- EE products that are regulated in the third and fourth subsection.
- steel that is regulated in the fifth subsection,
- aluminium that is regulated in the fifth subsection,
- copper alloys that are regulated in the fifth subsection

It is forbidden to produce, import, export and sell EE products that contain arsenic or arsenic compounds when the content of the substance in the product's homogeneous individual parts is greater than or equal to 0.1 percent by weight.

The prohibition in the third section does not apply to semiconductors and copper foil for printed circuit boards that contain arsenic.

It is forbidden to produce, import, export and sell steel, aluminium and copper alloys that contain more arsenic or arsenic compounds than what is given below.

- steel with a content of higher than 0.35 percent by weight of arsenic in the product's homogeneous individual parts,
- aluminium with a content of higher than 0.4 percent by weight arsenic in the product's homogeneous individual parts,
- copper alloys with a content of higher than 4 percent by weight of arsenic in the product's homogeneous individual parts

The rules that already exist for arsenic and arsenic compounds in the Product Regulations will be retained as they are. The existing prohibition against arsenic in antifouling compounds and wood sets no limit values for the content of arsenic and it is not desirable to be softening up the existing prohibition.

Arsenic and arsenic compounds in cosmetics are regulated in a separate body of regulations that are justified solely on the basis of health-related considerations. An exemption will first of all be made in the regulation of hazardous substances for consumer products with an arsenic content that are regulated in the Cosmetics Regulations. The environmental authorities will, at a later point in time, assess whether there is a need and the possibility for still stricter regulation of arsenic in cosmetic products due to regard for the environment.

In relation to the body of regulations in the EEA Agreement and the WTO's body of regulations, regulation of arsenic 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. In our assessment, the health and environmental goals that are being attempted to be achieved stand in proportion to the expenses and disadvantages the regulation inflict on the stakeholders, and other means are not deemed to be appropriate.

In our assessment no specific legal regulations/total harmonisation requirements exist in the EEA body of regulations for chemicals involving arsenic that pose an impediment to the proposed regulation.

Further regulation is being proposed for arsenic and arsenic compounds because arsenic is on the priority list, and it is already regulated for use as a biocide, for example as an antifouling compound and wood preservative. Arsenic is found in the environment. Expanded regulation will cause reduced occurrences in the environment,

as well as reduce the risk of damage to health.

8) Economic assessment

Examples of known application areas for arsenic that will be encompassed by the regulation are plastic/PVC products, including garden items, travel/recreational items, building materials, window glass and wallpaper, joint sealant and textiles, products of steel, aluminium and copper alloys, as well as EE products. The list is not exhaustive; all application areas within the scope that do not fall under the exemptions will be encompassed by the regulation. It is being proposed that existing rules that are mentioned under point 5 be retained as they are and hence will not be changed through this regulation.

SFT's surveys and computations show that the emissions of arsenic have been significantly reduced in recent years, and today comprise approx. 1 ton from products. No emissions from electrical and electronic products are included in this figure.

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 does involve an enormous number of products. Hence the total quantity is significant. There have been return arrangements established for EE products, but many small EE products and toys are not connected. Arsenic from discarded EE products cannot 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 (including TDK Green Procurement Standard Document (ver.4, August 1, 2007)). These standards are both internationally accepted standards and contain requirements for restricted content of substances hazardous to health and the environment in components for EE products (including arsenic compounds), which large international enterprises are posing today of their subcontractors. Many manufacturers of EE products are familiar with these standards and products thus exist that fulfil the requirements, even though not all producers are necessarily in a condition to fulfil them. The limit values in the proposal for regulation are with respect to requirements in these standards. We thus know that EE products can be delivered with parts respecting these requirements. It thus also ought to be possible to acquire documentation showing that the products fulfil the given standards.

Furthermore, we have also proposed exemptions where no satisfactory alternatives exist. These exemptions build to a large degree on exemptions in standards as well as on consultative statements.

The proposal for regulation of arsenic will contribute to reducing the emissions significantly. The content of arsenic in the products is in many cases due to the lead content in the products, and regulation of lead will thus also reduce the arsenic content of the products. Where it is not possible to replace arsenic and arsenic compounds, we are of the opinion that it is possible to limit the content of these compounds.

Broad regulation of the use of arsenic in consumer products will be the best means because there is a desire to reduce the emissions significantly on the short run, cf. national goals. On the overall, our assessment is that the measure will not cause significant economic costs. On the basis of the documentation that we have, we expect that the benefit will be greater than the costs.

Assessments of impact associated with regulation of hazardous substances in consumer products.

Bisphenol A

1) Substance or substance group

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

2) Known application areas

- Polycarbonate plastic (in food-related and other packaging, electronic devices, medical equipment, means of transport, CD discs, greenhouse walls, building glass, returnable bottles, baby bottles, protective helmets)
- Dental tooth filling materials
- PVC (as a hardener, catalyst, binding agent, stabiliser for, for example, floor covering, building plastic, garden hoses, baby bottles, toys, travel items)
- Epoxy resin production (many different epoxy resins including joint-free floors, EE products, coatings on boxes and paper, building structures, powder lacquer)
- Paint, lacquer, glue, (binding agents, hardeners)
- Thermal paper
- Polyol for production of polyurethane
- Production of tetrabromobisphenol A (TBBPA, flame retardant agent) (can be degraded to bisphenol A under certain environmental conditions)
- Other, including brake fluid and vehicle tyres

The list also contains application areas/products that are only for occupational use and such are not encompassed by regulation of bisphenol A in consumer products.

Quantity utilised of the substance

2003 max. 71.5 tons. Declared to the Product Register (PR)

As at 6 March 2006 (declaration obligatory in the PR). 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 quality (i.e. produced + imports - exports): max. 46.6 tons. The actual content in products that are sold in Norway is significantly higher. In addition to what is registered in the PR, there are many different products, particularly polycarbonate and other plastics (PVC) and painted products that contain bisphenol A. If it is presumed that the pattern of use for bisphenol A in Norway is about the same as in the EU, and that Norway's population comprises approx. 1.2 % of the EU's population, Norwegian turnover will be of an order of magnitude of 8200 tons/year.

SFT's analyses show a range in products from 2800 mg/kg to 2 mg/kg, with approx. half of them being under 10 mg/kg.

Number of stakeholders in Norway/large or small

- Many stakeholders, especially importers. Presumably a limited number of manufacturers.

Norwegian production/import/export

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

3) Description of risks to health and the environment

Bisphenol A degrades relatively easily in water, bioaccumulates slightly (LogKow 3.4, BCF 67), and is classified as an irritant and allergenic upon contact with the skin, plus is harmful to reproduction (Rep Cat 3, R62; possible risk of impaired fertility). Endocrine-disrupting effects have been shown (oestrogen effect). Bisphenol A is harmful to aquatic organisms, and it is being proposed that it be classified as R52 (harmful to aquatic organisms) in the EU in 30th ATP, due to endocrine-disrupting effects. New studies have been performed concerning the effects of extremely low doses on fish, and studies on snails are underway. The

substance is listed on the OSPAR "list of substances of possible concern", but not on the "list for priority action".

An EU risk assessment for the substance is available and its status is as follows:

The risk assessment was published in 2003 with multiple conclusions i); which is to say that there is a need for further testing and/or for more information on a number of points both concerning health and the environment. A conclusion i) involves a revision of the risk assessment as soon as the information that is desired is available. The information requirement applied, among other things, to further testing on snails and a study of the effects harmful to reproduction (developmental effects) for health.

A revised risk assessment for the environment (Final environmental addendum, draft for final written comment of September 2007) will now be concluded during the existing programme and continued under REACH.

The report shows that production and use in the EU of bisphenol A has increased significantly, from 690,000 tons/year during the years 1996-1999 to 1,149,870 tons/year for 2005/2006.

The report documents that bisphenol A has endocrine-disrupting effects on fish (including effects on egg hatching, vitellogenin production). There continues to be a conclusion i) in relation to possible effects on snails at lower concentrations (RAR draft of September 2007; page 153) than what is now used in the risk characterisation. The risk assessment will thus be revised under REACH when the final results of testing initiated by the UK authorities are available.

Monitoring data shows a substantial spreading in the environment in Norway (ref. SFT report TA 2006/2004, Fjeld et al.: Survey of selected new organic hazardous substances - brominated flame retardants, chlorinated paraffins, bisphenol A and triclosan).

Bisphenol A has been shown in sludge and sediments (silt) from Mjøsa, Drammenselva, Inner Drammen Fjord and in sediments along the Norwegian coast. Bisphenol A has also been shown in fish in the same areas.

Bisphenol A has been found in a number of types of freshwater fish, the highest concentration was found in brown trout in the Vormå River. Relatively high levels were also found in Mjøsa and Inner Drammen Fjord (ref. SFT report TA 2006/2004). Extremely little data exists for fish for the EU. There are some new measurements from the Netherlands (Vethaak et al 2002), the values for fish are lower here than the Norwegian values. The Norwegian measurement data has been sent to the reporter, and has now been included in the risk assessment.

The report concludes that the measured levels in fish are of the same order of magnitude as the calculated values, however it is recognised at the same time that the measured values fish are higher than those calculated (RAR draft of September 2007). The reporter however deems the measurement data to not be sufficiently comprehensive, and since they can neither be allocated with certainty to a local or the regional scenario, the calculated values are used.

In a newly published study, bisphenol A was shown in sediments from the Barents Sea (ref. SFT- report TA-2400/2008, Bakke et al., Survey of selected organic hazardous substances from the Barents Sea 2007). In other studies, some elevated levels in marine sediments have been shown in the vicinity of individual large population concentrations along the coast. Bisphenol A was also found in blue mussels and cod livers along the coast. In general, low levels were found in marine areas, both in sediments and in biological samples. The brominated flame retardant TBBPA is also a possible source for bisphenol A in the environment.

SFT is of the opinion that the data is comprehensive for Norway (coverage includes Mjøsa, Vormå, Øyeren, Inner Drammen Fjord) and that the worst case values from the measurements of fish also ought to be used in the risk characterisation for the regional scenario in addition to the calculated ones. This will also have consequences for the risk assessment for humans exposed via the environment (Man Via Environment). People who live in and eat a lot of fish from the areas with higher concentrations can be subjected to a higher exposure than the general population. For example, it has been documented that people in the Mjøsa area who eat a lot of fish from Mjøsa have higher concentrations of hazardous substances than the general population (bisphenol A was however not measured in this study) (Thomsen et al. Mol. Nutr. Food Res. 2008, 52, 000 – 000; "Consumption of fish from a contaminated lake strongly affects the concentrations of polybrominated diphenyl ethers and hexabromocyclododecane in serum"). In order to protect all population groups the worst case values for fish (14 µg/kg wet weight) should thus be used in the computations of the exposure of humans via the environment in the regional scenario. When the worst case value of 14 µg/kg wet weight is used in the regional scenario, the regional exposure becomes 2.9×10^{-5} mg/kg of body weight/day in comparison with a regional exposure in the EU RAR draft from September 2007 of 9.3×10^{-6} (table 1).

Table 1.

Bisphenol A regional exposure from the environment with data from EU RAR 2007 and fish data from Mjøsa, Vorma, Øyeren and Drammen Fjord

	Concentration in drinking water (mg/l)	Concentration in wet fish (mg/kg)	Concentration in plant roots (mg/kg)	Concentration in plant leaves (mg/kg)	Concentration in milk (mg/kg wet weight)	Concentration in meat (mg/kg wet weight)	Concentration in air(mg/m ³)	Total daily intake (mg/kg day)
Regional, EU RAR 2007	3.4×10^{-5}	2.3×10^{-3}	4.9×10^{-4}	1.1×10^{-4}	1.9×10^{-9}	5.8×10^{-7}	1.6×10^{-10}	9.3×10^{-6}
Regional fish data from Mjøsa, Vorma, Øyeren and Drammen Fjord	3.4×10^{-5}	1.4×10^{-2}	4.9×10^{-4}	1.1×10^{-4}	1.9×10^{-9}	5.8×10^{-7}	1.6×10^{-10}	2.9 section x 10^{-5}

It was also pointed out in the UK risk assessment that simultaneous exposure to several hormone-disrupting (oestrogens) substances may have additive effects (RAR draft of September 2007, page 116), but this is not captured by the present substance-by-substance approach. This is clearly a deficiency in the present risk assessments.

A revised risk assessment for *health* (updated risk assessment, draft of November 2007) was discussed at TC NES IV in December. The results from a study of effects harmful to reproduction are included and the reporter concluded that the previously selected NOAEL of 50 mg/kg bw/day will be retained and that there is no risk that consumers or people will be exposed via the environment. Some studies have however shown effects at lower concentrations, but these have been discarded by the reporter. Norway, Sweden and Denmark have commented that the low dose effects cannot be continued to be ignored. There is concern that the neurotoxic effects (effects on learning and memory of offspring) have not been examined to a sufficient degree in the study, which has been selected by the reporter as the gold-standard, definitive study of the reproductive toxicity of BPA, (which also is the study EFSA has used as a foundation in its most recent assessment). 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. Also, the fully newly updated NTP (National Toxicology Program) assessment of November 2007 concludes that there continues to be concerns connected with possible neurotoxic effects of bisphenol A and that further tests ought to be carried out (NTP Final expert panel report 26 November 2007 for bisphenol A “concludes “some concern” and “critical data need” for developmental neurotoxicity”). This supports the assessment of Norway, Sweden and Denmark that there continues to be uncertainty concerning the extent to which the risk assessment adequately takes into account the possible low dose effects.

The Norwegian Scientific Committee for Food Safety (Norwegian Initials: VKM) was commissioned by the Norwegian Food Safety Authority to evaluate the low dose studies where a possible effect has been shown in experiments on animals involving the development of the nervous system of newborns (effects on learning and memory). VKM concluded that there are significant deficiencies in the studies, but that the results from the studies also give grounds for concern. VKM is thus proposing that a new study be carried out to examine possible effects on the development of the nervous system in newborns (OECD Test Guideline 426), instead of changing the NOAEL value of 5.0 mg/kg of body weight/day that EFSA is currently using to set the ADI (Acceptable Daily Intake). The drawback of performing a new study is that it would take at least 2-3 years before the results are ready. When the NOAEL value of 5.0 mg/kg of body weight/day is compared with children's exposure for bisphenol A from consumer products, food and the environment (0.013 mg/kg of body weight /day) the factor of safety emerges as being 380. Due to the uncertainty connected with possible effects on the development of the nervous system in newborns upon exposure to bisphenol A, SFT is of the opinion that this factor of safety is too low.

SFT has performed a study of the content of free (residual) bisphenol A from plastic where bisphenol A is included in the polymer. Free, unreacted bisphenol A will be available to leach out of the plastic. The study showed that even though many products contain low quantities of free bisphenol A, individual products were identified with some very high quantities of free bisphenol A. SFT sent the report from the product study to the reporter, and focused in particular on children's mittens that had elevated levels of free bisphenol A and asked that the supplemental exposure for children who use such mittens and may put them in their mouths (corresponding to what is done for toys and children's products for exposure to phthalates) be included. The daily exposure for bisphenol A from children's mittens is computed to be 0.0033 mg/kg of body weight/day. In this computation a value of 98.2 mg bisphenol A/kg mittens was utilised (data from Molab A/S. Hazardous substances in selected products, report, KR-030803, 18 May 2006). Furthermore, it is presumed that mittens are used for 100 days (winter season), the quantities of mittens that are put into the mouth are 50 grams and that the child weighs 15 kg. The reporter rejected however the inclusion of children's mittens as one of the exposure scenarios in the risk assessment. The justification was that the number of samples was too small to be representative for the Norwegian market, and that it regardless was not representative for the EU. The study showed in addition that three products (one bag and two sealants) had extremely high levels of free bisphenol A. Unreacted freely available bisphenol A will be able to leach out to the surroundings when the products are in use or when they end up as waste. The product types and the levels of free bisphenol A that were identified in the Norwegian study were not included in the EU's risk assessment.

In table 2 below the total regional exposure for bisphenol A is computed inclusive exposure from mittens and the total consumer exposure from the EU RAR draft 2007.

Table 2

Total exposure for bisphenol A:

Exposure scenarios	mg/kg of body weight/day
Regional fish data from Mjøsa, Vormo, Øyeren and Drammen Fjord	0.000029
Consumer exposure (child) from EU RAR 2007	0.01
Child's exposure from mittens	0.0033
Total	0.013

In the risk characterisation in table 3, the lowest LOAEL value was used from the studies where neurotoxic effects have been shown (effects on learning and memory in offspring). The computation shows that when the LOAEL value of 0.1 mg/kg of body weight/day is used and exposure to bisphenol A from mittens is included in the total regional exposure, the safety factor becomes 8, which is far under the recommended limit of 100.

Table 3

Risk assessment of total exposure to bisphenol A minus exposure at the workplace

Exposure	mg/kg of body weight/day	LOAEL*	MOS
Total regional exposure from table 2	0.013	0.1	8

*LOAEL based on neurotoxic effects (effects on memory and learning in offspring) ref. proposed footnote in EU RAR from Denmark.

The proposal for regulation sets a limit for free availability (i.e. residual monomers) of 0.005 percent by weight. The proposal does not involve a prohibition on consumer products that contain bisphenol A, but rather sets a limit for the content of residual monomers since unreacted bisphenol A in plastic will be available for leaching out into the environment or exposure of consumers who are using the products.

Bisphenol A may be released to the environment from the production process, and by the use of the substance in the production of a number of raw plastic 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 shown endocrine effects both in fish and in snails. The primary source of terrestrial exposure is the spreading of sludge from sewage treatment plants. There is a need for risk reduction measures with respect to the environment for several application areas. With respect to consumers, there is no direct exposure, however polycarbonates and epoxy resins that contain bisphenol A are included in many consumer products. A Norwegian study shows large variations in freely available bisphenol A in different products on the market, varying from a quantity of 10mg/kg free monomers to approx. 2500 mg/kg. Potential consumer exposure may occur if residual monomers become available or if the polymer is damaged or degraded, for example in epoxy resin-based paint, wood putty and glue. Emissions to the environment from products throughout their lifespan or as waste may cause indirect exposure of humans. The size of the emissions in Norway of bisphenol A from products is not known.

4) Occupational use

- Polycarbonate plastic in medical electronic equipment
- Production of tetrabromobisphenol A
- Polyol for production of polyurethane

Application areas that are only for occupational use will not be addressed any further in this overview.

5). Consumer products where bisphenol A is currently regulated or where assessments/processes are occurring internationally

Here, only bodies of regulations are being named that involve products within the scope of the proposal.

- Cosmetics: Cosmetics Regulations, Annex IIB: Prohibited (established by the Ministry of Social Affairs and Health Services, now the Ministry of Health and Care Services)

On-going processes/assessments internationally:

Canadian authorities have performed a risk assessment of bisphenol A that is currently undergoing consultations. The risk assessment concludes that the level of bisphenol A in hermetic boxes intended for food for small children must be lower or be replaced with less hazardous substances, and that a prohibition must be introduced on baby 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 computed 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 have halted sales of children's products of plastic with bisphenol A.

In the US, the healthcare authorities have signalled a new attitude towards bisphenol A exposure. They are not excluding a possible danger of effects on the development of the nervous system and on behaviour with foetuses, newborns and small children who are exposed to bisphenol A daily from baby bottles and food packaging.

The EFSA (European Food Safety Authority) has also announced that they will reassess their assessment of bisphenol A based on the risk assessments performed by Canada and the US. Such would be able to lead to a change in EFSA's setting of the ADI (Acceptable Daily Intake) for bisphenol A.

RoHS 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 bisphenol A, has been sent out for consultations. 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 RoHS.

6) Alternatives

We know that PVC products without bisphenol A are commercially available.

The regulation that is being proposed is a limitation of the quantity of free bisphenol A (residual monomers of bisphenol A) in the products. According to Plastic Europe, the quantity of residual monomers will vary in the different polymer materials depending upon the source of the polymer.

7) Proposal for further regulation

It is being proposed that the content of bisphenol A in consumer products shall be regulated in the following manner:

It is forbidden to produce, import, export and sell consumer products that contain freely available bisphenol A (CAS No. 80-05-7), when the content of the substance in the product's homogeneous individual parts is greater than or equal to 0.005 percent by weight.

The prohibition does not apply for:

- *jointless floors,*
- *brake fluid,*
- *thermal paper,*
- *dental tooth filling materials*

There is at present no regulation of bisphenol A in the Product Regulations. In the Food Packaging Regulations, bisphenol A is regulated with a limit for migration in materials that come into contact with food products. Most of the products in this category comply with these boundaries with a good margin.

Bisphenol A in cosmetics is regulated in a separate body of regulations that is justified solely on the basis of health-related considerations. An exemption will first of all be made in the regulation of hazardous substances for consumer products with a bisphenol A content that are regulated in the Cosmetics Regulations. The environmental authorities will assess at a later point in time whether there is a need and possibility for still stricter regulation of arsenic in cosmetic products due to regard for the environment.

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. Production and consumption of bisphenol A in the EU are extremely high and have increased significantly in the past decade. Products have been identified in the Norwegian market that contain some extremely high levels of freely available bisphenol A. Free, unreacted bisphenol A will be available to leach out into the environment and to expose consumers. Such products with a high content of free bisphenol A that have been detected by the Norwegian study (for example children's mittens) are not included in the EU risk assessment. There continues to be uncertainty concerning the lower threshold values for effects on the environment and in our assessment also for effects on health as regards neurotoxic effects. The substance is classified as harmful to reproduction and it is uncertain when a satisfactory basis of data will exist, Norway (in addition to Sweden and Denmark) is 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 the possible availability of new, adequate studies of neurotoxic effects. Data also shows that bisphenol A is widespread in the Norwegian environment and is present in, among other things, freshwater fish in relatively high levels, something that also is a source of exposure for humans. When the threshold values for neurotoxic effects are utilised and exposure to bisphenol A BPA from mittens are included in the total regional exposure, the safety factor becomes 20, which is far under the recommended limit of 100. Bisphenol A is an endocrine-disrupting substance. Simultaneous exposure to multiple endocrine-disrupting substances may give additive effects, which is something that has not been captured in the current risk assessments. The substance fulfils the criteria for the generation target (based on effects like endocrine-disrupting/toxic to reproduction and it is monitored in the environment and biota in Norway). This substance satisfies all the criteria for the use of the precautionary principle as mentioned in the introduction.

In relation to the body of regulations in the EEA Agreement and the WTO's body of regulations, regulation of bisphenol A 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. In our assessment the health and environmental goals that are being sought to be achieved stand in proportion to the disadvantages the regulation entails for the stakeholders, and other means are not deemed to be appropriate.

In our assessment, no specific legal regulations/total harmonisation requirements exist in the EEA body of regulations for chemicals for bisphenol A that pose an impediment to the proposed regulation.

8) Economic assessment

Examples of known application areas that will be encompassed by the regulations are polycarbonate plastic, epoxy resin products, paint, lacquer, glue and PVC. The list is not exhaustive and all application areas within the scope that do not fall under the exemptions will be encompassed by the regulation. We are proposing to exempt some additional products from the regulation in the short run either because no alternatives exist or because these alternatives would be extremely expensive.

Broad regulation of the use of bisphenol A in consumer products will be the best means because there is a desire to reduce the emissions significantly in the short run. The proposal will contribute to reducing the dangers to health and the environment connected with the portion of bisphenol A that is most easily available in the products. The costs of this regulation are thus reduced in relation to a total prohibition on bisphenol A content in the products. On the overall, it is our assessment that the measure will not entail significant economic costs. On the basis of the documentation we have, we expect that the benefit will be greater than the costs.

Assessment of consequences connected with regulation of hazardous substances in consumer products.

Lead and lead compounds

1) Substance or substance group

Lead and lead compounds

2) Known application areas

Metallic lead:

- lead accumulators/storage batteries
- Building materials (roof covering, etc.)
- Sailboat keels and other ballast uses in boats
- Lead belts for diving
- Cable coatings
- Alloys (incl. soldering alloys)
- Fishing tackle (for commercial and recreational activities).
- Ammunition
- Weights (balancing of automobile tyres, curtain weights, etc.)
- Lead used as shielding against radiation
- Electrical equipment, light sources, soldering tin
- Jewellery, rivets in clothing
- Other, including lead glass windows

Chemical lead compounds:

- Glass (picture tubes, light sources, crystal glass)
- Stabiliser (particularly in imported PVC plastic products such as building items such as profiles for doors and windows, wallpaper, floor covering, rook gutters, pipes, contacts, cables, toys, travel items, plastic boxes, recreational items, textiles)
- Pigments (in paint and lacquer)
- Pigments (in plastic)
- Glazes/enamels
- Glue/binding agents
- Blast sand
- Lubricants
- Laboratory chemicals (precipitating chemicals, process assistives, accelerants)
- Print colours
- Packaging
- Other (aviation petrol, automobile tyres, brake linings)

The list also contains application areas/products that are only for occupational use, and such will not be encompassed by regulation of lead in consumer products.

Registered quantities in Norway (2005) (arrow up/down: Trend in consumption from 2004) (ref. SFT- report TA 2296/2007 - Hazardous substances in products - data for 2005).

Metallic lead:

- Metallic products (workshop and building) 6544t↑
- Fishing tackle 232t ↓
- Other met. products 226t

Chemical compounds:

- Paint, lacquer, etc. 8t ↓
- Stabiliser in PVC 16t ↓
- Glazes 4.8 ↑
- Other (glue, binding agents, precipitating chemicals, process assistives, print colours, accelerants, lubricants) 24t ↑

Norwegian production/import/export:

Use of lead as a stabiliser in PVC plastic has been reduced in Norwegian production. Lead may occur in imported products, particularly products of PVC plastic and products of recycled plastic. We do not have an overview of the quantity of imported products that may contain lead.

3) Description of risks to health and the environment

Lead bioaccumulates and is not degradable. Lead is toxic in low concentrations, having both acute and chronic health and environmental effects. Lead is acutely toxic to humans and chronic lead poisoning can have neurotoxic and immunological effects. May damage the haematopoietic system. Lead is harmful to reproduction, may result in brain injuries, foetal injuries, damage to fertility and blood creation in humans. Children are more exposed than adults. Lead and lead compounds accumulate in the skeleton and soft tissues. They are very toxic for aquatic organisms, and may cause undesirable long-term effects in the aquatic environment.

Lead has been shown in humus layers, sediments in lakes and fjords, soil, species of animals.

This substance satisfies all the criteria for the use of the precautionary principle as mentioned in the introduction.

Total national emissions of lead in 2005 were computed to be 240 tons. Emissions from contaminated soil of approx. 10 tons are not included. The emissions of lead in 2005 are dominated by emissions from products and comprise approx. 88 % of the total emission in Norway (approx. 212 tons). In addition, emissions of lead to municipal drainage and sewer sludge were computed to be 3.6 tons in 2005. Emissions from are essentially due to the use of ammunition, which is primarily used by the Armed Forces.

We have however limited information on the content of lead in imported products. Analyses performed by SFT in 2005 and 2006 show findings of lead in different imported plastic products (including plastic-coated textiles, leisure time articles, toys). Emissions from these products are thus not included in the compute emission figures mentioned above. Increased import of products, particularly PVC products from countries with no regulation of the area, will comprise a more significant source of lead emissions in the Norwegian market as we gradually gain control over the most significant sources at present.

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 receive satisfactory handling as waste, they will not comprise a significant problem. The use of metallic lead that will comprise a problem is associated with products that are difficult to collect after use. This will typically concern fishing tackle, curtain weights and ammunition.

4) Occupational use

- Lead in products that may come into contact with food (food product packaging)
- X-ray protection
- Blast sand
- Lubricants
- Laboratory chemicals
- Print colours
- Lead in components in vehicles
- Paint
- Fertiliser

Application areas that are only for occupational use will not be addressed any further in this overview

5) Consumer products where lead is already regulated at present or where assessments/processes are occurring internationally

Here, only bodies of regulations are being named that involve products within the scope of the proposal

- Cosmetics: The Cosmetics Regulation, appendix IIA: Prohibited. Trace quantities permitted: In cosmetics 20mg/kg. In toothpaste 1 mg/kg (established by the Ministry of Social Affairs and Health Services, now the Ministry of Health and Care Services)
- Electrical and electronic products: Limit of 0.1 %. Exemptions for fluorescent lamps 10mg various alloys, monitoring and control instruments (for example GPS equipment). The RoHS Directive/Product Regulations, section 3-18, appendix V (established by the Ministry of the Environment).
- Paint: Prohibition on lead carbonates and lead sulphates. Exemptions may be given for restoration. Dir. 89/677/EEC art 17 and 18. Product Regulations, section 7-1 (individual decisions). (Established by the

Ministry of the Environment).

- Packaging: The sum of lead, cadmium, mercury and hexavalent chrome shall not exceed 100mg/kg. Exemptions for packaging produced solely of lead crystal glass. Dir. 94/62/EC art 11/Product Regulations, section 3-11 (established by the Ministry of the Environment).
- Batteries: Prohibition on built-in batteries with over 0.4 % lead (with exemption in appendix II to chap. 3 in the Product Regulations). Dir 91/157/EEC, Dir 93/86/EEC and Dir 98/101/EC. Product Regulations, section 3-14 b, cf. 3-13 d (established by the Ministry of the Environment). New Battery Directive Dir. 2006/66/EC has recently been established.
- Petrol: Prohibition on lead quantities over 0.005 g/l. Dir 98/70 and Dir 03/17. Product Regulations, section 3-16, appendix IV (established by the Ministry of the Environment). The limit has been set because some lead occurs naturally in crude oil. Lead may not be added to petrol in Norway or the EU.
- Lead shot: Prohibition on lead shot. Product Regulations, section 2-5 (established by the Ministry of the Environment).

On-going processes/assessments internationally:

We are not aware of any on-going processes or assessments concerning restrictions under the present body of regulations for this substance internationally. Work is being done on a voluntary risk assessment.

6) Alternatives

Denmark has a separate regulation that regulates the use of lead and lead compounds for selected application areas. This means that we know that there are satisfactory alternatives for a number of application areas that are encompassed by this proposal, including building materials, paint and fishing tackle for private use.

The following alternatives are available:

- Building materials: Aluminium and rubber polymer (www.catsub.dk)
- Cord solder: Lead-free cord solder (www.catsub.dk)
- Stabiliser in PVC: Stabiliser based upon calcium zinc
- Paint: Alternative to paints with lead content are available(www.catsub.dk)
- Fishing tackle: other metals such as steel and iron for example

Commercially available products exist without lead that fulfils the necessary technical requirements for the product, also for most of the other application areas.

7) Proposal for further regulation

It is being proposed that the content of lead in consumer products shall be regulated in the following manner:

It is forbidden to produce, import, export and sell consumer products that contain chemical lead compounds when the content of the substance in the product's homogeneous individual parts is greater than or equal to 0.01 percent by weight.

The prohibition does not apply for:

- tobacco,
- ammunition, apart from lead shot, which is regulated in section 2-5 of the Product Regulations,
- yellow lead for restoration of historical objects,
- fuel for aeroplanes,
- paint that is regulated in section 2-5 of the Product Regulations,
- corrosion protection paint with less than 250 ppm lead,
- antifouling paint with less than 1250 ppm lead,
- crystal and lead glass,
- products that are produced of recycled glass that are regulated in the third subsection
- glazes and enamels on products that must be presumed to not come into contact with foodstuffs,
- packaging, batteries and electrical and electronic products and equipment that are regulated in sections 3-11, 3-13 to 3-14 and 3-17 to 3-19 of the Product Regulations.

It is forbidden to produce, import, export and sell the following consumer products that are produced of recycled glass that contains chemical lead compounds when the content of the substance in the product's homogeneous individual parts is greater than or equal to 0.05 percent by weight:

It is forbidden to produce, import, export and sell the following consumer products that contain metallic lead when the content of the substance in the product's homogeneous individual parts is greater than or equal to 0.01 percent by weight:

- products for hobby purposes,
- tea candles and other candles,
- curtain weights,
- products for decorative purposes, including jewellery,

- *products for covering roofs and flashing for buildings,*
- *fishing equipment for recreational use.*

It is being proposed that the rules that already exist for lead and lead compounds in the Product Regulations be kept as they are. Some prohibitions/regulations set no limit value for lead content, and some regulations are harmonised with the EEA body of regulations. It is not desirable to soften up the existing regulations.

Lead and lead compounds in cosmetics are regulated in a separate body of regulations that are justified solely in the basis of health-related considerations. It is proposed that in the beginning an exemption be made to the regulation of hazardous substances in consumer products for products with a lead content that are regulated in the Cosmetics Regulations. The environmental authorities will assess at a later point in time whether there is a need and possibility for still stricter regulation of lead in cosmetic products due to regard for the environment.

In relation to the body of regulations in the EEA Agreement and the WTO's body of regulations, regulation of lead 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. In our assessment the health and environmental goals that are being sought to be achieved stand in proportion to the disadvantages the regulation entails for the stakeholders and other means are not deemed to be appropriate.

In our assessment no specific legal regulations/total harmonisation requirements exist in the EEA body of regulations for chemicals involving lead that pose an impediment to the proposed regulation.

Further regulation is being proposed for lead and lead compounds because lead is on the priority list. Lead is found in the environment. Lead is prohibited today in paint (lead carbonates and lead sulphates), as well as in shot. Expanded regulation will reduce occurrences in the environment, as well as reduce the risk of damage to health.

Denmark already has a prohibition against lead and lead compounds. The present proposal is in line with the prohibition in Denmark.

For most of the application areas, commercially available alternative products exist on the market.

8) Economic assessment

Examples of known application areas for lead that will be regulated are building materials, stabilisers in PVC, pigments in plastics, paint and lacquer, fishing tackle, use as weights, glue and binding agents. The list is not exhaustive, and application areas that are not known will also be encompassed by the regulation. It is being proposed that existing rules that are mentioned under point 5 be retained as they are and hence will not be changed through this regulation.

The proposed regulation will reduce the remaining quantity of emissions of lead from products by approx. half. It will cause reduced emissions to water, and reduce future costs associated with waste management. At the same time, it must be expected that there will be some increased expenses in the transition to alternatives, particularly other stabilisers in PVC.

Broad regulation of the use of lead and lead compounds in consumer products will be the best means because there is a desire to reduce the emissions significantly on the short run, cf. national goals. On the overall, it is our assessment that the measure will not entail significant economic costs. On the basis of the documentation we have, we expect that the benefit will be greater than the costs.

Assessment of consequences connected with regulation of hazardous substances in consumer products.

Hexabromocyclododecane (HBCDD)

1) Substance or substance group

Hexabromocyclododecane (HBCDD)

2) Known application areas

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

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

The list may also contain application areas/products that are only for occupational use and these are not encompassed by the regulation of HBCDD in consumer products.

Of a total of approx. 70 different brominated flame retardants, the three substances decabromodiphenyl ether (decaBDE), hexabromocyclododecane (HBCDD) and tetrabromobisphenol A (TBBPA) comprise the largest part. Total consumption of brominated flame retardants in Norway is estimated to be 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. In EE products, HBCDD is used primarily in the production of cabinets. 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 have been registered in building materials. In 2005, approx. 4 tons of HBCDD was registered, being used in insulation materials (for building of houses and roads, etc.). It is estimated that the consumption of HBCDD in insulation materials has not changed significantly since 2005. Cellular rubber in the Norwegian market contains approx. 15 tons of brominated flame retardants, and it is assumed that 1.5-3 tons of this is HBCDD. There are reasons to presume that HBCDD is present in some imported products that we do not have an overview of.

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

There are significant imports of means of transport and EE products to Norway. There is hardly any production of means of transport in Norway, but there are many importers. There are some manufacturers of construction products and EE products in Norway, and many importers.

Norwegian production and use of construction products (insulation materials) with HBCDD has been reduced significantly since 1992. There is no production of EPS or XPS with HBCDD in Norway today. In contrast, some special products are imported, for example wet room panels, which contain HBCDD. Wet room panels sold on the Norwegian market in 2007 are estimated to contain a total of 12 tons of HBCDD. This estimate is however very uncertain. EPS granulate with HBCDD is produced in Norway, but it is exported for use in the professional supplies market. Norwegian production of cellular rubber has ceased, however 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 contained HBCDD. Estimates from 2007 suggest that consumption of cellular rubber is approx. 250-300 tons. This gives 15 tons of brominated flame retardants if an average content of 5 % is reckoned. The brominated flame retardants other than HBCDD are primarily used in cellular rubber in the Norwegian market today, and it is estimated that 1.5-3 tons of HBCDD are used annually in cellular rubber in Norway

EE products contain only minor quantities of HBCDD, however the substance is able to be included in many imported products such as inexpensive consumer electronics and electrical toys produced in Asia. HBCDD is used in EE products preferentially in HIPS plastic (high impact polystyrene). SFT ordered selected importers of EE products in the autumn of 2007 to send in information on the content of, among other things, HBCDD in their products. Only one of the companies reported back that they actually have HBCDD in their products. There is obviously great variation in knowledge and emphasis on brominated flame retardants such as HBCDD

at companies that import EE products, and the scope of the use of HBCDD in these types of products are hence difficult to survey.

Large quantities of HBCDD have been used previously in upholstery production. It has been stated that its use has now been terminated. The European textile industry states in comments on the EU's work on a risk reduction strategy for HBCDD that this compound is first and foremost utilised in technical textiles and upholstery. Typical end products are specified as being padded furniture, curtains, interior textiles and textiles for, for example, interiors of automobiles. A number of these application areas are only relevant in specific cases, such as for use in institutions. It cannot be excluded that imported products may contain HBCDD without the importer being aware of such.

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

3) Description of risks to health and the environment

HBCDD is extremely toxic to aquatic organisms, persistent and may cause undesirable long-term effects in the environment. In the EU's working group for classification and labelling, no resolutions have been adopted concerning health classification of HBCDD, however a proposal does exist concerning classification with R64 "May cause harm to breast-fed babies". In June of 2003, it was agreed that the substance should be environmentally classified and labelled with N; R 50-53 and that lower specific concentration boundaries would be set 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 in top-level predators even in remote areas. In addition, the substance is bioaccumulating and toxic.

Long-range transport. Measured in sediments, plants and animals. (ref. SFT report TA 2096/2005, Fjeld et al.: Survey of selected new organic hazardous substances 2004). Found in animals high in the food chain, far from point sources and in the Arctic.

Emissions from products: Emissions from brominated flame retardants from products are computed 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 waters in Switzerland, in blue mussels from Lofoten and Varanger, in cod livers from Northern Norway, in cod and ringed seals from Svalbard, in marine birds and birds eggs from Northern Norway and in polar bears from Greenland and Svalbard. These findings suggest that HBCDD is transported long-range via the atmosphere. Use of products that contain HBCDD among the small populations in these areas cannot explain the measured amounts. Since the highest concentration of HBCDD has been measured in marine mammals, such indicates that HBCDD is biomagnified. More recent data indicates that the levels in marine mammals are increasing. A Norwegian study of the occurrence of, among other things, HBCDD over a period of 20 years in eggs from species of arctic seabirds from Northern Norway and Svalbard also show an increase in the levels from 1983 to 2003 (ref. SFT report TA 2134/2005, Gabrielsen et al.: Temporal trends of brominated flame retardants). The persistence of HBCDD has been documented by it repeatedly being found in remote areas and accumulating in top-level predators. The EU's PBT working group has decided that HBCDD is a PBT substance (persistent, bioaccumulating and toxic).

This substance satisfies all the criteria for the use of the precautionary principle as mentioned in the introduction.

4) Occupational use

- Granulate that is exported

Application areas that are only for occupational use will not be addressed any further in this overview.

5) Consumer products where HBCDD is already currently regulated or where assessments/processes are occurring internationally

HBCDD in consumer products is not regulated in Norway and the EU at present.

On-going processes/assessments internationally:

RoHS 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, among them HBCDD, 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 RoHS.

The EU has presented a proposal for a risk reduction strategy for HBCDD. It proposes preparing a proposal to include HBCDD in the POPs Convention¹ and that HBCDD be included as a prioritised compound in Annex X of the Water Framework Directive (Directive 2000/60/EC). It is proposed the further work be conducted with HBCDD under REACH. An estimate of the time before regulation of HBCDD will exist in the EU is thus uncertain.

6) Alternatives

When there is a need for flame retardants for insulation materials (EPS/XPS), it has in the interim turned out that it is difficult to find alternatives. This is because flame retardants are being demanded that are effective at low concentrations because the products have a very low specific gravity. For some application areas, other building materials will be able to be used, for example glass wool, stone wool, etc. Requirements for fire safety in buildings may also be complied with by 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 a product's composition and/or design. 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 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 also performed at the same time. Other flame retardants may be both less expensive and more expensive than HBCDD.

7) Proposal for regulation

It is being proposed that the content of hexabromocyclododecane (HBCDD) in consumer products shall be regulated in the following manner:

It is forbidden to produce, import, export and sell consumer products that contain hexabromocyclododecane (HBCDD) (Cas. No. 25637-99-4, 3194-55-6) when the content of the substance in the product's homogeneous individual parts is greater than or equal to 0.1 percent by weight.

In relation to the body of regulations in the EEA Agreement and the WTO's body of regulations, regulation of HBCDD 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. In our assessment the health and environmental goals that are being sought to be achieved stand in proportion to the disadvantages the regulation entails for the stakeholders, and other means are not deemed to be appropriate.

In our assessment no specific legal regulations/total harmonisation requirements exist in the EEA body of regulations for chemicals involving HBCDD that pose an impediment to the proposed regulation.

8) Economic assessments

Examples of application areas that will be encompassed by the regulation are EE products, construction products (cellular rubber, insulation materials - EPS/XPS, glue/lacquer/joining compound, wet room panels, special products) and textiles. Use in means of transport is outside the scope of this proposal. The list is not exhaustive; all application areas within the scope will be encompassed by the regulation.

¹ [Stockholm Convention \(the POP Convention\): convention concerning persistent organic pollutants \(POPs\)](#)

With a broad regulation it is expected that the greatest costs will be connected with regulation of granulate that contains HBCDD (export of semi-finished goods) and the use of means of transport. The granulate concerned is not a consumer product and we are proposing exempting the means of transport in our proposed regulation. These two application areas will thus not be impacted by the regulation. For individual special products for piping insulation (cellular rubber) the alternatives may be somewhat more expensive.

General regulation of the use of HBCDD in consumer products would be the best means because the desire is to reduce the emissions significantly in the short run. On the overall, it is our assessment that the measure will not entail significant economic costs. On the basis of the documentation we have, we expect that the benefit will be greater than the costs.

Assessment of consequences connected with regulation of hazardous substances in consumer products.

Cadmium and cadmium compounds

1) Substance or substance group

Cadmium(Cd) and cadmium compounds

2) Known application areas

- Surface treatment of metal/cadmium plating
- Pigments in plastic (incl. EE products)
- Stabiliser in PVC (essentially imported PVC products such as leisure time items, wallpaper, children's toys)
- Paint and lacquer
- Textiles
- Batteries
- Sacrificial anodes
- Fertiliser
- Packaging
- Tobacco
- Sewage treatment agents

In recent years there have been increased imports of products, particularly plastic products from countries with no regulation of the area. This will be able to cause an increased quantity of cadmium in the Norwegian market.

The list may also contain application areas/products that are only for occupational use and these are not encompassed by the regulation of hazardous substances in consumer products.

3) Description of risk to health and the environment

Cadmium is acutely and chronically toxic to humans and animals. Cadmium is very acutely toxic for aquatic organisms, particularly in freshwater, and acutely toxic for mammals. Cadmium compounds give chronic toxic effects in many organisms, even in very small concentrations. Most cadmium compounds are carcinogenic. Cadmium is bioaccumulative 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 shown in vegetation, surface soil and animals, fjords and watercourses.

This substance satisfies all the criteria for the use of the precautionary principle as mentioned in the introduction.

In 2005 the total national emissions of cadmium were 1.8 tons, of this the emissions from products, as well as emissions of cadmium in sewer sludge and discharges, are computed to be 0.44 tons, i.e. approx. 24 %. There is little to indicate that the cadmium emissions will be reduced significantly up to 2010. The emissions from products come primarily from sacrificial anodes and fertiliser. In recent years there have been increased imports of products, particularly plastic products from countries with no regulation of the area. This will be able to cause an increased quantity of cadmium in the Norwegian market. The quantity of cadmium in imported products is not included in the computed emissions figures.

4) Occupational use

- PVC packaging on medical equipment
- Pigments
- Stabiliser
- Surface treatment

Application areas that are only for occupational use will not be addressed any further in this overview.

5) Consumer products where cadmium is already regulated today or where assessments/processes are occurring internationally

Here, only bodies of regulations are being named that involve products within the scope of the proposal.

- Cosmetics: The Cosmetics Regulation, appendix IIA: Prohibited. Trace quantities permitted: In cosmetics 5mg/kg. In toothpaste 0.1 mg/kg (established by the Ministry of Social Affairs and Health Services, now the Ministry of Health and Care Services).
- Pigments: Prohibition on placing in the marked, but a limit of 0.1 percent by weight if a high zinc content. In addition to a prohibition on its use for colouring connected to a number of listed fabrics/fabric blends. Dir 91/338/EEA. Product Regulations, section 2-11 (established by the Ministry of the Environment).
- Stabiliser: Prohibited in a number of listed products. For import, export and sale the prohibition applies for over 0.01 %. Dir 91/338/EEA. Product Regulations, section 2-12 (established by the Ministry of the Environment).
- Surface treatment of metal: Prohibited for a number of listed sectors/application areas. Exemption for electrical contacts. Dir 91/338/EEA. Product Regulations, section 2-13 (established by the Ministry of the Environment).
- Batteries: Certain prohibitions on cadmium in batteries. Product Regulations, sections 3-13 and 3-14 (established by the Ministry of the Environment).
- Electrical and electronic products: Product Regulations, sections 3-17 to 3-19 (established by the Ministry of the Environment).
- Packaging: The sum of lead, cadmium, mercury and hexavalent chrome shall not exceed 100mg/kg. Exemptions for packaging produced solely of lead crystal glass. Dir 94/62/EC art 11/Product Regulations, section 3-11 (established by the Ministry of the Environment).

On-going processes/assessments internationally:

We are not aware of any on-going processes or assessments concerning restrictions under the present body of regulations for this substance internationally.

6) Alternatives

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

7) Proposal for further regulation

It is being proposed that the content of cadmium and cadmium compounds in consumer products shall be regulated in the following manner:

It is forbidden to produce, import, export and sell consumer products that contain cadmium or cadmium compounds when the content of the substance in the product's homogeneous individual parts is greater than or equal to 0.01 percent by weight.

The prohibition does not apply for:

- tobacco,
- fertiliser,
- red and yellow glass for special purposes where no alternatives exist,
- electrical contacts for any application area that have been surface-treated with cadmium or cadmium compounds in order to ensure the reliability that is required for the device in which they are installed,
- paint and lacquer with a high zinc content that is regulated in the third subsection,
- use of cadmium in colouring agents, as a stabiliser in products and for surface treatment of metal, provided that such is used due to safety-related grounds,
- sacrificial anodes,
- cadmium in packaging, batteries and electrical and electronic products and equipment that are regulated in the Product Regulations, sections 3-11, 3-13 to 3-14 and 3-17 to 3-19,
- Cadmium zinc sulphide (CI 77205),
- Cadmium sulphoselenide and cadmium selenide (CI 77202),
- Cadmium sulphoselenide (CI 77196).

The rules that already exist for cadmium and cadmium compounds in the Product Regulations will be retained as they currently are because they are in line with the harmonised EEA body of regulations.

Cadmium and cadmium compounds in cosmetics are regulated in a separate body of regulations that is justified solely on the basis of health-related considerations. An exemption will first of all be made in the regulation of hazardous substances for consumer products with cadmium content that are regulated in the Cosmetics Regulations. The environmental authorities will assess at a later point in time whether there is a need for still stricter regulation of cadmium in cosmetic products due to regard for the environment.

It is possible to regulate the substance in consumer products with the exemptions that follow explicitly from the directives mentioned above. General exemptions for safety-related reasons must be maintained (pigments, stabiliser, surfacetreatment).

In relation to the body of regulations in the EEA Agreement and the WTO's body of regulations, regulation of cadmium 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. In our assessment the health and environmental goals that are being sought to be achieved stand in proportion to the disadvantages the regulation entails for the stakeholders and other means are not deemed to be appropriate.

In our assessment no specific legal regulations/total harmonisation requirements exist in the EEA body of regulations for chemicals involving cadmium that pose an impediment to the proposed regulation.

Further regulation of cadmium and cadmium compounds is being proposed because cadmium is on the priority list and is already strictly regulated in Norway and the EU with restrictions as a stabiliser and pigments in different types of plastic, PVC product groups and in paint. Cadmium has been found in the environment. Expanded regulation will reduce occurrences in the environment, as well as reduce the risk of damage to health.

8) Economic assessment

Examples of known application areas for cadmium that will be regulated are surface-treated metal/cadmium plating, pigments in plastic, stabiliser in PVC, paint and lacquer, textiles and sewage treatment agents. The list is not exhaustive, application areas within the scope that are not known will also be encompassed by the regulation. It is being proposed that existing rules that are mentioned under point 5 be retained as they are and hence will not be changed through this regulation.

The use of cadmium is already strictly regulated in Norway, but the formulation of the regulation is unmanageable and provides room for loopholes, particularly for imported products. It is difficult to check whether the products comply with the requirements in the existing regulations. The primary purpose of expanded regulation is to close holes in the existing regulation, as well as simplify the enforcement of the body of regulations. The substance occurs chiefly in imported products from, among other places, Asia. According 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. Broad regulation of the use of cadmium in consumer products will be the best means because there is a desire to reduce the emissions significantly on the short run, cf. national goals. On the overall, it is our assessment that the measure will not entail significant economic costs. On the basis of the documentation we have, we expect that the benefit will be greater than the costs.

Assessment of consequences connected with regulation of hazardous substances in consumer products.**Medium-chain chlorinated paraffins (MCCP)****1) Substance or substance group**

Medium-chain chlorinated paraffins C14-C17 (MCCP), Cas. No. 85535-85-9

Is the most-used Cas. No. for this group (most specific for MCCP). Various Cas. numbers exist that are more unspecific and include MCCP, but which in addition encompass short-chain or long-chain chlorinated paraffins.

2) Known application areas*Primary 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 (primarily wallpapers, floor covering, cables, leisure time and travel items)
- Lubricants/lubricating oils for metalworking
- Leather impregnation
- Other, including rubber and carbon-free paper

The list also contains application areas/products that are only for occupational use and such are not encompassed by regulation of MCCP in consumer products.

Quantities and distribution of MCCP:

Material flow analyses from 2005 estimate 54-64 tons of MCCP in chemicals/products registered in the Product Register (PR). Imports in set products/goods are not included in these figures. The table below shows the distribution in the Norwegian survey (quantities and percentages) and the percentage distribution in all types of products in the EU. The Norwegian survey gives however a biased picture of the use of MCCP in PVC because there are comprehensible imports of different PVC products that are not declared in the Product Register. Analyses of fixed, imported products show large quantities of MCCP in cables, construction products such as wallpaper and travel and leisure time articles (sacks, bags, suitcases, camping chairs, etc.).

Category	Sales in Norway 2005 tons	Distribution of use in the EU 2003
Polyester (Softener/fire retardant)	15 – 20 (31 %)	6.5 %
Insulation/sealant materials /glue *	30 – 35 (55 %)	* in total 15 %
Paint and lacquer products, surface treatment*	1	
PVC	Not registered in the PR and in Norwegian-produced PVC	60 %
Lubricants/lubricating oils	approx. 5 (8 %)	15 %
Leather impregnation	?	2.5 %
Other use, including rubber	Approx. 3 (5 %)	
In total	54 -64	

No information is available on the quantity of MCCP sold in Norway in 1995. In Sweden, a reduction has been reported in the quantity of MCCP sold from approx. 700 tons in 1995 to approx. 150 tons in 2003. If we presume a corresponding trend in Norway as in Sweden from 1995 up to today, the quantity of MCCP sold in products in Norway is roughly estimated to be 280 tons in 1995, and consequently has been reduced up to the present. MCCP in imported goods is however not included in these figures. No use of MCCP in Norwegian-produced PVC has been registered, but it has been found in many different imported soft PVC products. In the EU, the use of MCCP in PVC has been reduced, whereas in the other application areas, including sealing/joining agents, it is increasing.

Number of stakeholders in Norway/large or small

We have hardly any overview of the number of stakeholders. But there are a limited number who use MCCP in

their production. In contrast, there are many importers who import products that may contain MCCP. *Norwegian production/import/export (Ref.: the Product Register)*

MCCP is not being produced in Norway. In contrast, MCCP is utilised in the production of products/goods in Norway. We have no overview of possible exports 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).

3) Description of risk to health and the environment

Medium-chain chlorinated paraffins have a substantial potential for bioaccumulation (bioconcentration factor of up to 1087 has been measured in fish). MCCP is persistent. MCCP has been shown in the food chain, including in fish, cow's milk and in human breast milk. The EU's risk assessment has demonstrated a risk to the aquatic environment and the terrestrial environment.

It is being proposed that MCCP be classified as very toxic to aquatic organisms and may cause undesired long-term effects in the aquatic environment (R50/53). In addition, it is being proposed that they be classified with the risk phrase "May cause harm to breast-fed babies," (R64) and "Repeated exposure may cause skin dryness or cracking" (R66).

The risk assessment/PBT evaluation concludes that there is a need for more data in order to determine whether the substance in purely technical terms satisfies the B criteria (bioaccumulating). Further testing of bioaccumulation has been decided upon, but the results of the individual test in the proposed test programme are deemed to be able to 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 be made to introduce regulations based upon precautionary principle considerations. This justification is reinforced by in any event some of the MCCP compounds having PBT properties. The EU Commission points out in the minutes from the RRS meeting in April 2008 that there is a need for more information and testing. This is justified by it possibly indicating that the uptake of MCCP via food is important because higher values are found than one could expect on the basis of the BCF values.

Measurements in the environment and biota may be crucial for a final evaluation of the potential of the substance 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 measured in the environment using reliable methods and has been shown 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. MCCP was recently (November 2007) included in an action plan for the Baltic Sea on the basis of demonstrated occurrences in sediment and biota.

Monitoring data shows substantial spreading in the environment in Norway of both short-chain (SCCP) and medium-chain chlorinated paraffins (MCCP) ref. SFT report TA 2006/2004, Fjeld et al.: Survey of selected new organic hazardous substances - brominated flame retardants, chlorinated paraffins, bisphenol A and triclosan). The compounds have been shown in blue mussels and cod livers along the Norwegian coast from Inner Oslo Fjord to Varanger Fjord. Furthermore, they have been found in fish from Drammen Fjord, Mjøsa and in Øyeren. The substances have also been shown in sediments from Drammenselva and Drammen Fjord, Outer Oslo Fjord, Trondheim and Tromsø harbours and other marine stations along the coast. Furthermore, the substances have been found in fish and in sediments from Mjøsa. The highest known level in Norway was observed in sediments from Drammen Fjord. In sediments, medium-chain chlorinated paraffins dominate, whereas in fish mostly the short-chain chlorinated paraffins have been found. MCCP is also found in fish and in samples of fish from Øyeren, MCCP dominated. Both short-chain and medium-chain chlorinated paraffins have been found in run-off from rubbish disposal sites. This data on occurrences in the Norwegian environment has been an important basis for proposing regulation of MCCP.

SFT has shown 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, bags and camping chairs. Many of these products are produced in low-cost countries in Asia. Use of MCCP is inexpensive and production is simple and is based in part on old technology. With continually increasing consumption and imports from Asia, the trend in consumption ought to be followed up on.

Presumably the most important product areas are insulation/sealants/glue and imported PVC. The direct effect

on health is greatest for its use in metal working, however such is only a working environment problem and is not included in consumer products. The primary problem is a general spreading of MCCP to the environment from many different products by their use and as waste. Because MCCP is included in so many different products that over time become waste, the quantities remaining in waste will have significance to the spreading of MCCP to the environment.

4) Occupational use

- Lubricants for metalworking
- Polyester for lifeboat production
- Electrical cables (both consumer product and occupational use)
- Floor covering with a requirement for fire safety

Application areas that are only for occupational use will not be addressed any further in this overview.

5) Consumer products where MCCP is already being regulated today or where assessments/processes are occurring internationally

There are no regulations on the use of MCCP in consumer products today.

On-going processes/assessments internationally:

RoHS 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, among them MCCP, 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 RoHS.

The consulting firm Entec has on behalf of the British environmental authorities (Defra) prepared a draft of an updated risk analysis for the environment (ref. MCCP updated stage 4 report (draft) Feb. 2008) that was presented at the RRS meeting in the EU in April. It concluded that there was a need for a combination of several measures. No individual measure exists that limits the risk and simultaneously does not involve significant drawbacks in relation to costs, technical efficiency and the potential risks of the use of alternatives.

In the report, measures were summarised in two groups: 1) measures justified by measurable risks and 2) measures justified on the basis of the precautionary principle. The updated version of the risk assessment concludes that measures must be evaluated based upon the precautionary principle, due to possible PBT properties and the consequences of waste from products in the environment.

The EU has presented a proposal for a risk reduction strategy for MCCP. It proposes that MCCP should be included as a prioritised compound in Annex X to the Water Framework Directive (Directive 2000/60/EC). The EU Commission has also prepared a proposal for regulation of MCCP for, among other things, metalworking and impregnation in the leather industry. It is proposed the further work should be conducted with MCCP under REACH. An estimate of the time before regulation of MCCP will exist in the EU is thus uncertain.

6) Alternatives

MCCP is used primarily as a fire retardant and softener and is used a lot because it is inexpensive and simple to produce. There are alternatives for both application areas, but they are for the most part more expensive. A number of the alternatives, particularly as flame retardants, also have negative environmental effects however. Where MCCP is only used as a softener, there are a number of satisfactory alternatives both for health, the environment and technical properties. The phthalate DINP is a good alternative in PVC and is not so much more expensive. For paint and rubber/polymers (exempt PVC) and leather impregnation, among other things long-chain chlorinated paraffins (LCCP) are an alternative, however it is more expensive. We refer in general to the RRS for MCCP (February 2008) from Defra, UK, where a number of alternatives have been evaluated.

Alternatives for fire retardants exist, but they are more expensive and trialkylphosphate, which may be used in PVC, has risky environmental properties. MCCP is used in PVC primarily only as a fire retardant in soft PVC. MCCP has not been registered in the production of PVC by Norwegian industry. We are not aware of any requirements for fire retardants in PVC products for consumers. Uses of MCCP include incorporation in floor

coverings and wallpapers, but Norwegian building codes (and the EU's Construction Products Directive) do not place any such fire safety requirements on construction products. The building code only poses a framework requirement and such may be satisfied by other building technology solutions. MCCP is used, among other things, in flame-proof floor coverings and cables, however these are used primarily for professional use where such are especially called for.

For many of the relevant PVC products that contain MCCP, there are alternative materials that have better environmental properties. It is not necessary to make these products of PVC. Such also applies for sealants and joining material.

7) Proposal for regulation

It is being proposed that the content of MCCP in consumer products shall be regulated in the following manner:

It is forbidden to produce, import, export and sell consumer products that contain medium-chain chlorinated paraffins, C14-C17 (MCCP) (Cas. No. 85535-85-9), when the content of the substance in the product's homogeneous individual parts is greater than or equal to 0.1 percent by weight.

The prohibition does not apply for products where there is a special need for a flame retardant (fire safety) and no satisfactory alternatives exist.

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

The EU Commission has prepared a proposal for regulation of MCCP for, among other things, metalworking and impregnation in the leather industry in addition to MCCP being included in the priority list in Annex X to the Water Framework Directive (Doc:ES/12f/2007 Rev. 1). The proposed application areas involve consumer products to a slight degree and thus do not cover our primary objective of regulating MCCP in consumer products.

Regulation of MCCP is being proposed because the substance is on the priority list, some of the individual compounds have PBT properties and have been found in the environment and shown in the food chain, as well as in human breast milk. MCCP is used to a slight degree in Norwegian production, however it occurs in imported products, particularly in PVC products. Satisfactory alternatives to MCCP as softeners exist and in some areas as a flame retardant.

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

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. In our assessment the health and environmental goals that are being sought to be achieved stand in proportion to the disadvantages the regulation entails for the stakeholders, and other means are not deemed to be appropriate.

In our assessment no specific legal regulations/total harmonisation requirements exist in the EEA body of regulations for chemicals involving MCCP that pose an impediment to the proposed regulation.

8) Economic assessment

Examples of known application areas that will be encompassed by the regulation are PVC, paint, lacquer, surface treatment (primarily solvent-based), glue, insulation and sealing materials, polyester (softener/fire retardant), leather impregnation and rubber. The list is not exhaustive, all application areas within the scope will be encompassed by the regulation.

The proposal for regulation will reduce emissions of MCCP by approx. half of the quantity that is registered in the Product Register, and a significant reduction of MCCP in imported set products is expected. Replacement of MCCP as a softener with alternative substances will not cause increased costs of any significance. Replacement

of MCCP with alternative fire retardant substances will entail increased costs, for example in sealing/joining agents and soft PVC. Other alternative methods exist however for sealing (for example mineral wool) and PVC. Furthermore, we are proposing an exemption for products where there are special requirements for fire safety and where there are no satisfactory alternatives. This will entail the costs for the use of alternative flame retardants being reduced significantly.

Broad regulation of the use of MCCP in consumer products will be the best means because there is a desire to reduce the emissions significantly on the short run. The proposal for regulation will be able to result in some increased costs, however it will give a significant reduction of MCCP for the environment, and reduce the risk of damage to health. On the overall, it is our assessment that the measure will not entail significant economic costs. On the basis of the documentation we have, we expect that the benefit will be greater than the costs.

Assessment of consequences connected with regulation of hazardous substances in consumer products.

Musk xylene

1) Substance or substance group

Musk xylene, Cas. No. 81-15-2

2) Known application areas

- air cleaners
- automobile wax
- floor and furniture polishing products
- detergents and cleansers
- fabric softeners
- cosmetics, perfume, toilet articles and shampoo

The most important sources of emissions are detergents and cosmetics. Among the consumer products, emissions from households, including from washing machines, showers and cleaning, are the most important contributors to health and environmental problems. Musk xylene is in the process of being phased out in Norway and Europe. The emissions are presumed to go via municipal drainage systems. Simplified, it is reckoned that the annual emissions correspond to the annual sales of the substances. Total emissions of musk compounds are thus estimated to be 0.5 tons in 2005, of this musk xylene comprised 0.3 tons.

Norwegian production/import/export

No basis has been found for changing figures for the quantity of the substances sold in Norway in relation to the figures that have been used in recent years. This is based upon information on the trend in consumption in Europe up to the year 2000 and shows a significant decline in the use of both musk xylene and musk ketone. Figures from Norway have been estimated on the basis of these figures, as a representative portion of the European consumption. There is much that indicates that the reduction in use of musk xylene in products on the European and Norwegian markets have also continued after the year 2000, without there being a basis for estimating this reduction with reasonable certainty. If the trend in Europe from 1995 – 2000 is extrapolated up to 2006, such would give a Norwegian share of an estimated 80 kg/year of musk xylene sold in products in Norway in 2006 (ref. SFT report TA 2296/2007 - Hazardous substances in products - data for 2005).

Musk compounds are not produced in Norway. Musk xylene is primarily used in detergents and soap. Musk xylene is used to a very slight degree in detergents produced in Norway. The substance is in the process of being phased out in Norway and Europe. China is the most important source of the European imports.

3) Description of risk to health and the environment

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 a carcinogenic effect" and as dangerous for the environment with risk phrase R 50/53; "very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment".

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. Musk xylene has been assessed to fulfil the vPvB criteria (very persistent, very bioaccumulative substance). Musk xylene is furthermore classified as carcinogenic in category 3 (Carc. Cat 3).

Musk xylene satisfies all the criteria for use of the precautionary principle as mentioned in the introduction.

The compounds have been shown in aquatic environments, sludge and sediments, fish and mussels (in Europe). Tests on rainwater, blue mussels, reefs and sewer sludge showed no nitromusk compounds.

4) Occupational use

Detergents and cleaning agents that are only for occupational use

Application areas that are only for occupational use will not be addressed any further in this overview.

5) Consumer products where musk xylene already is regulated today or where assessments/processes are occurring internationally

Here, only bodies of regulations are being named that involve products within the scope of the proposal.

- Cosmetics, perfume, toilet articles and shampoo: Cosmetics Regulations, appendix 3: Substances with conditional permission in cosmetics and body care products (cf. section 6 in the regulations) (**established** by the Ministry of Social Affairs and Health Services, now the Ministry of Health and Care Services)

Musk xylene: All cosmetic products with the exemption of mouth hygiene products

- a) 1.0 % in perfumes as a finished product (fine fragrance)
- b) 0.4 % in "eau de toilette" and after-shave lotions
- c) 0.03 % in other products

- Detergents, including automobile wax, floor and polishing agents with a cleansing effect: Product Regulations, section 3-10 (established by the Ministry of the Environment). There are requirements for labelling of musk compounds in detergents, implemented in the Product Regulations, section 3-10 (the Detergent Regulation).

On-going processes/assessments internationally:

We are not aware of any processes or assessments concerning restrictions under the present body of regulations currently on-going for this substance internationally.

6) Alternatives

Use as scent substance. Can be replaced by other substances of possible omitted.

7) Proposal for further regulations

It is being proposed that the content of musk xylene in consumer products shall be regulated in the following manner:

It is forbidden to produce, import, export and sell consumer products that contain musk xylene (Cas. No. 81-15-2), when the content of the substance in the product's homogeneous individual parts is greater than or equal to 0.05 percent by weight.

The prohibition does not apply for detergents that are regulated in sections 3-8 to 3-10 of the Product Regulations.

Musk xylene in cosmetics is regulated in a separate body of regulations that is justified solely on the basis of health-related considerations. It is proposed that in the beginning an exemption be made to the regulation of hazardous substances in consumer products for products with a musk xylene content that are regulated in the Cosmetics Regulations. The environmental authorities will assess at a later point in time whether there is a need and possibility for still stricter regulation of musk phenol in cosmetic products due to regard for the environment.

In relation to the body of regulations in the EEA Agreement and the WTO's body of regulations, regulation of musk xylene 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. In our assessment the health and environmental goals that are being sought to be achieved stand in proportion to the disadvantages the regulation entails for the stakeholders, and other means are not deemed to be appropriate.

In our assessment no specific legal regulations/total harmonisation requirements exist in the EEA body of regulations for chemicals involving musk xylene that pose an impediment to the proposed regulation.

8) Economic assessment

Examples of known application areas for musk xylene that will be regulated include automobile wax and floor-furniture polish products that do not have a cleansing effect and air cleaners. The list is not exhaustive and all application areas within the scope that do not fall under the exemptions will be encompassed by the regulation. Existing rules that are mentioned under point 5 will be retained as they are and hence will not be changed through this regulation.

It is being proposed that musk xylene be regulated because the substance is on the priority list and has been

shown in the environment. The substance is strictly regulated in cosmetic products. We are not aware of the substance being used in any Norwegian production. The substance may occur in imported products, primarily from China. It is presumed that imports from countries outside Europe will increase in the future. In order to avoid an increase in products with musk xylene on the market, we are of the opinion that it is important to have limits for the musk xylene content in the products.

Alternative fragrance substances exist, and musk xylene has no necessary function in the products. It will be relatively unproblematic to find suitable alternatives. Broad regulation of the use of musk xylene in consumer products will be the best means because there is a desire to reduce the emissions significantly on the short run, cf. national goals. Regulation will reduce occurrences in the environment, as well as reduce the risk of damage to health. On the overall, it is our assessment that the measure will not entail significant economic costs. On the basis of the documentation we have, we expect that the benefit will be greater than the costs.

Assessment of consequences connected with regulation of hazardous substances in consumer products.

Pentachlorophenol

1) Substance or substance group

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

2) Known application areas

- Imported impregnated wood (pallets with preparedness material in the Armed Forces)
- Imported impregnated textiles (occurs in awnings from Asia)
- May occur in imported items such as treated wood, fibre and fabric products, from countries outside the EU (for example possibly in decorative objects, rattan furniture)
- Leather

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

The list also contains application areas/products that are only for occupational use and such are not encompassed by regulation of pentachlorophenol in consumer products.

3) Description of risk to health and the environment

No risk assessment exists for pentachlorophenol in the EU.

Pentachlorophenol (PCP) is very toxic, not ready degradable and bioaccumulates in organisms. In addition, PCP is carcinogenic and very poisonous when inhaled. Under certain conditions the substance can give rise to the formation of dioxins. Pentachlorophenol is not ready degradable in the environment and bioaccumulates in organisms. The substance is classified as very toxic for aquatic organisms and may cause undesired long-term effects to the aquatic environment.

This substance satisfies all the criteria for the use of the precautionary principle as mentioned in the introduction.

Pentachlorophenol is absorbed by particles in soil, water and air and can be spread across large distances. Pentachlorophenol evaporates easily and is transported through the atmosphere. In areas with a cool climate, the substance will condense and be precipitated into the environment. Some pentachlorophenol is probably precipitated into the Norwegian environment in consequence of it being transported through the atmosphere. In the Arctic, pentachlorophenol has been found in the air, freshwater, seawater, ice and fish.

4) Occupational use

- Preparedness material in the Armed Forces

Application areas that are only for occupational use will not be addressed any further in this overview.

5) Consumer products where pentachlorophenol is already regulated today or where assessments/processes are occurring internationally

Here, only bodies of regulations are being named that involve products within the scope of the proposal.

- Cosmetics: Cosmetics Regulations, Annex IIB: Prohibited (established by the Ministry of Social Affairs and Health Services, now the Ministry of Health and Care Services)
- Products: Pentachlorophenol is currently prohibited in fabrics and fabric blends when it exceeds 0.1 percent by weight (Product Regulations, section 2-10), and is also regulated in leather and textiles (section 3-4) (established by the Ministry of the Environment).

On-going processes/assessments internationally:

We are not aware of any tangible processes or assessments occurring concerning restrictions under the present body of regulations for this substance internationally.

6) Alternatives

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

7) Proposal for further regulation

It is being proposed that consumer products with a content of pentachlorophenol shall be regulated in the following manner:

It is forbidden to produce, import, export and sell consumer products that contain pentachlorophenol (Cas. No. 87-86-5), when the content of the substance in the product's homogeneous individual parts is greater than or equal to 0.1 percent by weight.

The prohibition does not apply for textiles and leathers that are regulated in section 3-4 of the Product Regulations.

Pentachlorophenol in cosmetics is regulated in a separate body of regulations that is justified solely on the basis of health-related considerations. It is proposed that in the beginning an exemption be made to the regulation of hazardous substances in consumer products for products with a pentachlorophenol content that are regulated in the Cosmetics Regulations. The environmental authorities will assess at a later point in time whether there is a need and possibility for still stricter regulation of pentachlorophenol in cosmetic products due to regard for the environment.

In relation to the body of regulations in the EEA Agreement and the WTO's body of regulations, regulation of pentachlorophenol 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. In our assessment the health and environmental goals that are being sought to be achieved stand in proportion to the disadvantages the regulation entails for the stakeholders, and other means are not deemed to be appropriate.

In our assessment no specific legal regulations/total harmonisation requirements exist in the EEA body of regulations for chemicals involving pentachlorophenol that pose an impediment to the proposed regulation.

8) Economic assessment

Examples of known application areas for pentachlorophenol that will be regulated are impregnated wood and painted products. The list is not exhaustive, and all application areas within the scope that do not fall under the exemptions will be encompassed by the regulation. It is being proposed that existing rules that are mentioned under point 5 be retained as they are and hence will not be changed through this regulation.

It is being proposed that pentachlorophenol be further regulated. The substance fulfils the toxicity and bioaccumulation criteria, and is already regulated in fabrics and fabric blends, as well as in leather and textiles. It is not used in Norwegian production, however it may occur in imported products, especially in wood.

Expanded regulation will also cause set products to be encompassed, and reduce occurrences in the environment, as well as reduce the risk of damage to health. Regulation will contribute to avoiding future use. The primary purpose of expanded regulation is to cover up holes in existing regulations and to ensure that the emissions are halted. The substance occurs primarily in imported products. Most of the manufacturers have already found alternatives to pentachlorophenol in products. On the overall, it is our assessment that the measure will not entail significant economic costs. On the basis of the documentation we have, we expect that the benefit will be greater than the costs.

Assessment of consequences connected with regulation of hazardous substances in consumer products.

Perfluorooctanic acid (PFOA) and related compounds

1) Substance or substance group

- Perfluorooctanic 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, hydrofluoric acid of PFOA, Cas No. 335-66-0, methyl ester of PFOA, Cas No. 376-27-2, ethyl ether of PFOA, Cas No. 3108-24-5
- (*Perfluorooctyl sulphonate (PFOS) and PFOS-related compounds, chemical formula $C_8F_{17}SO_2X$ ($X = OH, metal\ salt, halogenide, amide$ and other derivatives including polymers)*)

(It is not being proposed that PFOS be regulated in this proposal, but the impact statement is to a large extent tied together with corresponding assessments of PFOS, hence this substance is included in the discussion))

2) Known application areas for PFOA and PFOS

- Textiles
- Impregnation agents
- Fluoropolymer and fluoroelastomer production
- Surface treatment (for example housekeeping products)
- Food product packaging (for example with the need for "grease proof" as in microwave popcorn bags, pizza boxes and sweets)
- Pans with non-stick coatings
- Cosmetics
- Floor wax, polish
- Paint and lacquer
- Fire-extinguishing foam (primarily PFOS)
- Surface treatment of metal/galvanisation bath (primarily PFOS)
- Hydraulic oil for airplanes (primarily PFOS)

The list also contains application areas/products that are only for occupational use and such are not encompassed by regulation of PFOA 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 included in products for which labelling is obligatory that are available to consumers. According to the fluoropolymer industry, PFOA is not added to consumer products. PFOA was used in fire-extinguishing foam, cosmetics, oils, paint, lacquer, biocides and pesticides (Moody and Field, 2000). According to a study carried out by the Norwegian Food Safety Authority in 2006, perfluoro compounds are not used in cardboard/paper packaging for so-called "fast food" in Norway, however in Europe and the US perfluoro chemicals continue to be used for impregnation of paper packaging.

SFT has performed a survey with the use of a literature study of PFOA in products in 2007 (ref. SFT report 2354/2007, Posner et al.: PFOA in Norway – survey of national sources 2007). It shows 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 primary conclusion in the survey is that the sources of occurrences of PFOA are difficult to survey and that the quantities of PFOA consumed in Norway are only partially known. A smaller portion, approx. 14 kg, is deemed to come from products, essentially consumer products, which primarily have been imported into Norway.

Product	Computed maximum quantities of PFOA consumed (kg/year)
Textiles, workclothes and athletics clothing produced in Norway	Unknown
Textiles, impregnated clothes for outdoor use	0.19 - 0.24
Footwear	0.5
Impregnated/coated paper	Unknown
Carpets	18 - 20

Wax	0.033
Polish	Unknown
Fire-extinguishing foam	Unknown
Paint and lacquer	1.5 - 1.7
Impregnation agents	0.8-4
Pesticides	Unknown

We find small quantities of PFOA, PFOS and their related compounds in textiles (up to 127 µg/m² (416 ng/g)) and impregnation agents (up to 456 ng/g) (ref. SFT report TA-2173/2006, Survey of perfluoroalkyl substances (PFAS) in selected textiles). Findings of PFOA in textiles in Norway show large variations, and most of the results lie in the range of approx. 1 – 35 µg/m² only two analyses show findings under 1 µg/m². The quantities are so low that we cannot reckon on PFOS, PFOA or individual salts and esters of PFOA having been added to the products. It probably involves low levels of contaminants. It is not acceptable that such serious hazardous substances as PFOS and PFOA are used in consumer products. Sinclair et al. report in 2007 the content of, among other things, PFOA in various pans with non-stick coatings. Analyses show findings of 19, 61, 67 and 287 µg/m² respectively.

According to ENVIRON International Corporation and DuPont (Washburn *et al.*, 2005), the total amount of PFOA concentration in carpets is computed to lie in the range of 0.2 µg/m² mg/kg of carpet fibre to 2 mg/kg of carpet fibre. Based on an average weight of carpets of approx. 1500 g/m², it corresponds to 290 – 2900 µg/m² of carpet.

3) Description of risk to health and the environment

PFOS and PFOA do not degrade in the environment. PFOS and PFOA have been shown everywhere in the environment. Evenset et al. (ref. Aquaplan NIVA report APN-414.3341, Evenset et al.: Hazardous substances in marine sediments, Isfjorden, Svalbard 2005 and Evenset et al.: Organochlorines, polybrominated diphenylethers and perfluorinated compounds in marine sediments from Isfjorden, Svalbard 2005) shown PFOS and PFOA as the most common perfluorinated compounds in sediments from Isfjorden in Svalbard. There have been no human activities at this location for 40 years, and the occurrence is probably due to long-range transport of the substances.

Monitoring data shows that the substances have been widely spread in the environment in the Nordic countries, including Norway (ref. TemaNord 2004, Berger et al.: Perfluorinated alkylated substances (PFAS) in the Nordic environment and SFT report TA 2096/2005, Fjeld et al.: Survey of selected new organic hazardous substances 2004). The substances have been shown in relatively high levels in human blood and in animals, including in the Arctic. A new SFT study (ref. SFT report TA-2184/2006, Odland et al.: Survey of "new" hazardous substances in human blood samples from Northern Norway, Northwest Russia and Siberia.) of human blood samples from Northern Norway and Siberia shows PFOS and PFOA in all the samples. PFOS is the dominating perfluorinated compound, however we also do find 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 Siberia.

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

PFOS is classified as Carc Cat 3; R40, Rep Cat 2; R61, Xn; R20/22, T; R48/25-R64 N; R52-53.

PFOA is classified as Carc Cat 3; R 40, Repr. Cat 2; R 61, T; R 48/23, Xn; R20/22, Xn; 48/22, Xi; R36, that is, the same health classification as PFOS, but no environmental hazard classifications at present.

4) Occupational use

- Fluoropolymer and fluoroelastomer production

Application areas that are only for occupational use will not be addressed any further in this overview.

5) Consumer products where PFOA and related compounds are already regulated today or where assessments/processes are occurring internationally

There is at present no regulation of this area in the EU or in Norway

On-going processes/assessments internationally:

The EU has adopted a directive against the use of PFOS in products where the provisions shall go into effect from at the latest 27 June 2008. The EU Parliament had desired to regulate PFOA along with PFOS, because PFOA was equally as worrisome of a substance as PFOS. The proposal was not adopted, but the Commission will make further risk assessments of PFOA and propose risk-reducing measures. It had been expected that Germany would present a draft for a risk assessment in February of 2008, but the point in time has been postponed.

6) Alternatives

The pollution control authorities of the US (US EPA) have made the large fluoropolymer producers in the US obligate themselves to a 95 % reduction in PFOA emissions from production and products within 2010, and 100 % within 2015.

7) Proposal for regulation

It is being proposed that the content of perfluorinated compounds in consumer products shall be regulated in the following manner:

It is forbidden to produce, import, export and sell consumer products that contain perfluorooctanoic acid (PFOA) and individual salts and esters of PFOA (Cas. No. 335-67-1, 3825-26-1, 335-95-5, 2395-00-8, 335-93-3, 335-66-0, 376-27-2, 3108-24-5) when the content of the substance in the product's homogeneous individual parts is greater than or equal to 0.005 percent by weight.

The prohibition in the first subsection does not apply for textiles, carpets and other coated consumer products that are regulated in the third and fourth subsections.

It is forbidden to produce, import, export and sell textiles and other coated consumer products that contain perfluorooctanoic acid (PFOA) and individual salts and esters of PFOA (Cas. No. 335-67-1, 3825-26-1, 335-95-5, 2395-00-8, 335-93-3, 335-66-0, 376-27-2, 3108-24-5) when the content of the substance in the product's homogeneous individual parts is greater than or equal to 50 µg/m².

It is forbidden to produce, import, export and sell carpets that contain perfluorooctanoic acid (PFOA) and individual salts and esters of PFOA (Cas. No. 335-67-1, 3825-26-1, 335-95-5, 2395-00-8, 335-93-3, 335-66-0, 376-27-2, 3108-24-5) when the content of the substance in the product's homogeneous individual parts is greater than or equal to 500 µg/m².

The proposal is justified by PFOA's very alarming health -related and environmental properties. PFOA has been shown everywhere in the environment and in human blood samples from around the globe. PFOA has the same classification for health as PFOS.

The proposed limits for the content of PFOA have been set on the background of analysis results and information from the industry concerning the content of PFOA in impregnation chemicals, as well as the requisite quantity used in order to achieve the desired properties. We are proposing regulating the content of PFOA in consumer products, exempting coated textiles, carpets and other materials, with a limit in terms of percentage weight. For textiles, carpets and other coated materials we propose regulating the quantity of PFOA with a limitation in the number of micrograms of PFOA per square metre of coated material. 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 the average weight for textiles and carpets (we have been informed that carpets weigh around 5 times as much as textiles), 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. At the same time, this differentiated regulation will ensure that we set as low of a limit as it is possible to comply with for textiles and other coated materials. It will be possible for the best of the products to fall under these limit values, whereas the products with the largest quantities will no longer be permitted.

PFOA is at present not regulated in the EU. In relation to the body of regulations in the EEA Agreement and the WTO's body of regulations, regulation of PFOA 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. In our assessment the health and environmental goals that are being sought to be achieved stand in proportion to the disadvantages the regulation entails for the stakeholders, and other means are not deemed to be appropriate.

In our assessment no specific legal regulations/total harmonisation requirements exist in the EEA body of regulations for chemicals involving PFOA that pose an impediment to the proposed regulation.

8) Economic assessment

Impregnated carpets, textiles, leisure time and travel articles, impregnated paper for food products (grease-proof), pans with non-stick coatings, impregnation agents, ski wax, and paint and lacquer are examples of application areas for PFOA that will be encompassed by the regulation. The list is not exhaustive, all application areas within the scope that do not fall under the exemptions will be encompassed by the regulation.

The primary portion of the 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 and that such are products that are imported into Norway. In order to avoid an increase in products with PFOA on the market, we believe that it is important to have limits for the PFOA content in products.

The proposed limit value for textiles will impede textiles with PFOA content from appearing on the market.

Broad regulation of the use of PFOA in consumer products will be the best means to achieve this. On the overall, it is our assessment that the measure will not entail significant economic costs. On the basis of the documentation we have, we expect that the benefit will be greater than the costs.

Assessment of consequences connected with regulation of hazardous substances in consumer products.

Triclosan

1) Substance or substance group

Triclosan, Cas. No. 3380-34-5

2) Known application areas

- Textiles (antibacterial agent in athletic socks, bicycle shorts, loose shoe soles,)
- shoe care agents
- Plastic products (including breadboards, tablecloths, fabrics in baby carriages, children's rainwear, toys)
- Paint
- Cosmetics and hygiene items (including toothpaste, mouthwash, deodorants, soap, foot spray)
- Animal care agents

The national consumption and emissions of triclosan in Norway are estimated to be 1.5 tons per year. Triclosan is used primarily in cosmetic products, however other uses of triclosan such as a biocide also occur. Sales of triclosan as a biocide are estimated to be under 0.1 tons per year. Triclosan in imported set products is not included in registered quantities.

3) Description of risk to health and the environment

Triclosan is classified as an irritant and dangerous for the environment with risk phrases R 36/38 (irritating to eyes and skin) and R 50/53 (very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment). The substance has the lowest limit value with respect to the environment (0.25 %). Triclosan may 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 shows an antibacterial effect, the "ready biodegradability" test is not relevant. Results for inherent degradation properties are also difficult to interpret since triclosan is adsorbed into sludge.

Triclosan has been shown in all sediment samples that have been analysed in Norway (ref. SFT report TA 2006/2004, Fjeld et al.: Survey of selected new organic hazardous substances - brominated flame retardants, chlorinated paraffins, bisphenol A and triclosan). The concentration is higher in sediment from municipal waste disposal sites and in Drammen Fjord, and lower in sediment from Mjøsa and Drammenselva. The concentration of triclosan in blue mussels and cod livers seems to be low, with the exemption of somewhat higher levels in cod livers from Ullerøy. Triclosan has also been shown in sludge from several municipal treatment plants along Oslo Fjord. In Sweden, in addition to having been shown in sediment and sludge, triclosan has also been measured in the air. This indicates that triclosan is spread both by water and the air. Triclosan has been shown in relatively high levels in moose livers and in fish in Sweden. In addition, triclosan has been shown in human breast milk. Influences from point sources seem to be less significant, while the effects from the households appear to be quite strong with respect to the levels of triclosan that have been found in the environment.

No risk assessment exists for triclosan in the EU under the existing programme. The EU's scientific committee (SCCP) has evaluated the substance, and recognises that there is substantial uncertainty connected with resistance to antibiotics. They are seeking more information and are of the opinion that it is important to have more knowledge of effects, because triclosan has been found in human breast milk. Triclosan has previously been evaluated as a candidate PBT (persistent, bioaccumulating and toxic) substance, however that it has not been evaluated further with respect to PBT since no relevant breakdown tests were present. It could not be evaluated as to whether the persistence criteria had been fulfilled. Triclosan fulfils however the toxicity and bioaccumulation criteria. Since widespread occurrences of triclosan have been shown in the environment, it indicates that the substance is not readily degradable. This data, the possibility for the development of resistance to antibiotics in bacteria and that consumer products are probably the greatest source for occurrences in the environment, indicates that the criteria for the generation target have been fulfilled. Triclosan in consumer products ought to be regulated.

This substance satisfies all the criteria for the use of the precautionary principle as mentioned in the introduction.

<p>4) Occupational use: Biocides. Triclosan has been notified and is included in the evaluation programme under the Biocide Directive. In the long run, triclosan will be regulated by the Biocide Regulations when it is marketed as a biocide.</p> <p>These application areas will not be addressed further in this overview.</p>
<p>5) Consumer products where triclosan already is regulated today or where evaluations/processes are occurring internationally <i>Here, only bodies of regulations are being named that involve products within the scope of the proposal.</i></p> <ul style="list-style-type: none"> • Cosmetics and hygiene items: Cosmetics Regulations, appendix 3: Substances with conditional permission in cosmetics and body care products (cf. section 6 in the regulations): soaps and products that are rinsed after use / other products, with limit values of 0.5 % / 0.3 % respectively (established by the Ministry of Social Affairs and Health Services, now the Ministry of Health and Care Services). <p>On-going processes/assessments internationally: We are not aware of any tangible processes or assessments occurring concerning restrictions under the present body of regulations for this substance internationally.</p>
<p>6) Alternatives Used as an antibacterial agent in textiles and plastic products. May in most cases be replaced by other substances or possibly be omitted.</p>
<p>7) Proposal for further regulation It is being proposed that the content of triclosan in consumer products shall be regulated in the following manner:</p> <p><i>It is forbidden to produce, import, export and sell consumer products that contain triclosan (Cas. No. 3380-34-5), when the content of the substance in the product's homogeneous individual parts is greater than or equal to 0.001 percent by weight.</i></p> <p>Triclosan in cosmetics is regulated in the cosmetics body of regulations that are justified solely due to health-related considerations. An exemption will first of all be made in the regulation of hazardous substances for consumer products with a triclosan content that are regulated in the Cosmetics Regulations. The environmental authorities will assess at a later point in time whether there is a need and possibility for still stricter regulation of triclosan in these products due to regard for the environment.</p> <p>In relation to the body of regulations in the EEA Agreement and the WTO's body of regulations, regulation of triclosan 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. In our assessment the health and environmental goals that are being sought to be achieved stand in proportion to the disadvantages the regulation entails for the stakeholders.</p> <p>In our assessment no specific legal regulations/total harmonisation requirements exist in the EEA body of regulations for chemicals involving triclosan that pose an impediment to the proposed regulation.</p> <p>It is being proposed that triclosan should be regulated because the substance has toxic properties and is bioaccumulating. Since widespread occurrences of triclosan have been shown in the environment, it indicates that the substance is not ready degradable. There is a possibility for developing antibiotic resistance in bacteria.</p>
<p>8) Economic assessment Examples of known application areas for triclosan that will be regulated are textiles, plastic articles and paint. The list is not exhaustive, all application areas within the scope that do not fall under point 5 are being proposed to be retained as they are and will not be changed through this regulation.</p> <p>Triclosan has no necessary function in most products. SFT assessed in 2007 whether other means such as a fee on triclosan in toothpaste could be used to reduce the emissions of triclosan, but has concluded that regulation of the quantity of triclosan in the product is the best means (ref. SFT ePhorte 2007/498, letter to the Ministry of the Environment: Assessment of fee on triclosan in all application areas). Regulation will reduce occurrences in the environment, as well as reduce the risk of damage to health. On the overall, it is our assessment that the measure will not entail significant economic costs. On the basis of the documentation we have, we expect that the benefit will be greater than the costs.</p>