

Ministry of the Environment
Postboks 8013
N-0030 OSLO

Norwegian Pollution Control Authority
Postboks 8100 Dep, N-0032 Oslo
Visiting address: Strømsveien 96

Telephone: (+47) 22 57 34 00

Fax: (+47) 22 67 67 06

E-mail: postmottak@sft.no

Internet: www.sft.no

Date: 08.07.2008

Our ref.: 2008/273 600

Your ref.:

Case administrator: Inger Grethe England, telephone: (+47) 22573441/
Pia Sørensen, telephone: (+47) 22573587

Proposal for regulation of certain hazardous substances in consumer products

SFT's assessment of consultative statements and proposal for administrative regulation

SFT is maintaining the proposal to strictly limit the substances bisphenol A, the brominated flame retardant HBCDD, medium-chain chlorinated paraffins (MCCP), musk xylene, pentachlorophenol, triclosan, the perfluorinated compound PFOA and the heavy metals arsenic, lead and cadmium in consumer products. We have on the basis of the consultative statements proposed certain changes to the limit values and scope of exemptions for these substances, at the same time secure that there is good protection of human health and the environment. It is being proposed that musk ketone and the tensides be omitted from the proposed regulation because new data does not indicate any risks. For the phthalate DEHP, tinorganic compounds and the brominated flame retardant TBBPA, it is recommended that national regulation should be awaited and that on-going processes in EU should be followed. SFT recommends establishing the proposed regulation as a new chapter in the Norwegian Product Regulations.

A proposal for a prohibition on certain hazardous substances in consumer products was sent out for comments on 31 May 2007 at the national, EU and WTO levels. SFT has received approx. 100 consultative statements from around the world. Many have objections to different parts of the administrative regulation, such as the scope and extent, precisely which substances ought to be regulated, limit values and exemptions.

Justification for the proposal

The substances for which regulation is being proposed 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 have to be regarded as irreversible. Hazardous substances accumulate in nature and in the food we eat. Hazardous substances are a serious threat to the health of future generations, to the environment and to future food safety. Hence it is extremely important to limit emissions of them. Monitoring data from Norway, in particular data from more recent screening studies shows a substantial dispersion of the substances in the environment.

Consumer products are especially important because consumers lack the requisite knowledge of the health and environmental problems of these substances connected with the use and disposal as waste. 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 exposed to emissions from consumer products, either directly or indirectly via the environment. Reducing the quantity of substances hazardous to health and the environment contained in products, is also an important measure in reducing the quantity of hazardous waste that arises.

When there is a need to reduce 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 much more difficult to intervene with measures that effectively impede the uncontrolled dispersion of hazardous substances at a later point in time once the products have been distributed throughout the market.

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. In order to achieve a limitation of risks, we thus believe it to be necessary, on the basis of an assessment employing the precautionary principle, to prohibit consumer products that contain more than the proposed limit values for the selected hazardous substances. The EU Commission has prepared a guidance document on the use of the precautionary principle in which they establish that the principle concerns primarily the well-being of future generations and an assessment of potential risk in a longer run. Furthermore, WTO member states have an independent right to determine the precise levels of their national protection for health and the environment that they consider to be appropriate. The member states of the WTO may introduce measures that result in higher level of protection than the international standards and recommendations involve.

The consultative comments

SFT has received comments of both general overall nature and comments on the individual substances. The consultative comments are summarised in appendixes 2 and 3. Many have taken a critical view of the proposal and are posing questions as to whether Norway has the right to introduce a national prohibition on the proposed substances. They refer to the EEA Agreement and the WTO regulations and refer in particular to the principles concerning justification, proportionality and non-discrimination. As agreed previously, these issues of principle are being evaluated by the Ministry, and are not encompassed by SFT's technical evaluations in appendix 1.

Many consultative comments have been received concerning the individual substances involving definitions, limit values, scope and extent, exemptions, etc. Most of the comments concern arsenic, lead, bisphenol A, the phthalate DEHP and the brominated

flame retardants HBCDD and TBBPA. The plastics industry and the electronics and ICT industry are the industries that have had the most comments on the proposal.

SFT's proposal

SFT is maintaining the proposal to limit the content of the substances bisphenol A, the brominated flame retardant HBCDD, medium-chain chlorinated paraffins (MCCP), musk xylene, pentachlorophenol, triclosan, PFOA and the heavy metals arsenic, lead and cadmium in consumer products. The proposal for regulation follows in appendix 5. Many consultative bodies have pointed out problems with implementing the proposed requirements for these substances, and that SFT's risk assessment of the individual substances does not fulfil the requirements in EU Directive 793/93, particularly with respect to the assessment of alternatives. SFT has proposed on the basis of the consultative comments certain changes to limit values and the scope of exemptions in the proposed regulation. At the same time, we have emphasised to make sure that there is good protection of health and the environment. SFT has taken the EU's risk assessments into account in the assessments, but has also emphasised occurrence in the Norwegian environment and in products on the Norwegian market. The justification for SFT's recommendation for each individual substance is given in appendix 1 and the impact assessments in appendix 4.

The ongoing processes in the EU with the regulation of DEHP and tinorganic compounds have now made substantial progress, and we are proposing to follow EU instead of national regulations. We are proposing, furthermore, that national regulation of the brominated flame retardant TBBPA be awaited on the basis of the conclusions in the EU's preliminary risk assessment. Once the final risk assessment for TBBPA is available, there will however be a need for a new assessment of the regulation of TBBPA. SFT is also proposing withdrawing the proposal to prohibit the three surfactants because the risk assessment concludes that there is no risk based upon present consumption. The available data concerning the effects/risks for musk ketone shows that it does not fulfil the requirements for prioritised substances, nor is the present consumption deemed to comprise any risk. We thus are proposing omitting this substance from the proposed prohibition.

Consequences of the proposal

Products are an important source of emissions. It has not been possible to quantify exactly how much of the emissions can be reduced as a consequence of the proposed limitations, however the information we do have indicates that regulation of hazardous substances in consumer products will limit potential emissions substantially.

This may be illustrated, among other things, by the following example: The consultative process shows that arsenic in electronics is a significant source of the total arsenic content in products. Since the use of arsenic is prohibited in wood impregnation, indications are that electronics now comprises the largest remaining source in products. Some 6.5 million electrical and electronic products (EE products) were sold in Norway in 2007. Most EE products contain arsenic. Even though the quantities in each individual unit are not so large, it involves a large number of products. Hence the total quantity of arsenic in products is substantial, and the potential for emissions correspondingly large.

During the consultative process there has been special attention paid to EE products. SFT has on the basis of the consultative comments raised the limit for arsenic and arsenic compounds for EE products. SFT's revised proposal for regulation is based on international standards that are utilised by a number of large manufacturers of EE products. There hence are products and manufacturers who fulfil the requirements even if not all manufacturers are in a position to fulfil them.

For most of the substances, we expect that the costs associated with the proposal will be relatively limited. This includes cadmium, musk xylene, triclosan and pentachlorophenol. 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.

Alternative products are available on the market that fulfil the proposed requirements for most of the application areas. In those cases where commercially available alternatives exist, we have made it a precondition that the restrictions should not involve costs of any significance.

In the formulation of the proposal, an emphasise has been placed on reducing the costs as much as possible without affecting the environmental effectiveness of the proposal in too large of extent. We are of the opinion that the proposal balances this relationship such that it is technically possible to fulfil the requirements, while at the same time the products of most concern regarding human health and the environment are not legal to sell. We are thus of the perception that the utility of the measure may be expected to be greater than its costs.

Inclusion in existing regulations

SFT is recommending that the proposed regulations be established as a new chapter in the Norwegian Product Regulations. The detailed specification of the scope and extent deviates from the rest of the Product Regulations, however we believe that such is necessary in order to clarify the scope of the proposed regulation. This has been done based upon the all the consultative statements received. In line with the general structure of the Product Regulations, SFT is proposing that the regulation also encompass exports of consumer products. We request that the Ministry of the Environment evaluate the proposal with respect to the main part of the EEA Agreement and whether the proposal to regulate exports should be maintained.

SFT's technical assessment of the consultative statements, summaries of the consultative statements, a revised impact assessment and an amended proposal for regulation are attached.

Sincerely

Ellen Hambro
SFT Director General

Sigurd Tremoen
Department Director

Appendixes:

- Appendix 1 SFT's technical assessment of the consultative statements
- Appendix 2 Summary of consultative statements – general comments
- Appendix 3 Summary of consultative statements – the individual substances
- Appendix 4 Impact assessments
- Appendix 5 Amended proposal for regulation