

Dear Sheila,

We refer to the letter from UNEP Chemicals of 9 December 2009. We hope you will find the following information useful.

In 2008 Norway introduced a general ban on Mercury in products with a few exemptions. The ban covers use of mercury in dental filling materials (amalgam) and measuring devices, as well as other products. You will find the unofficial translation of the Norwegian Product Regulations on the Norwegian Climate and Pollution Agency's website: [http://www.klif.no/seksjonsartikkel\\_30217.aspx](http://www.klif.no/seksjonsartikkel_30217.aspx). Mercury and mercury compounds are mainly covered by Section 2-6. Please also find attached an impact assessment prepared prior to introducing this ban.

A national clinical guideline for the use of dental filling materials has been issued by the Norwegian Directorate for Health and Social Affairs (2003): [http://www.helsedirektoratet.no/vp/multimedia/archive/00001/A\\_National\\_Clinical\\_G\\_1661a.pdf](http://www.helsedirektoratet.no/vp/multimedia/archive/00001/A_National_Clinical_G_1661a.pdf)

Industrial emissions of mercury is regulated by the The Norwegian Pollution Control Act, which is an enabling act. This means that the details in each case are outlined in discharge permits and regulations issued by the pollution control authorities. The Act was established for the purpose of preventing and reducing harm and nuisance from pollution. This is reflected in the main rule of the act, which says that pollution is forbidden, unless it is specifically permitted by law, regulations or individual permits. Emissions of priority hazardous substances such as mercury will only be permitted if warranted by special circumstances. When enterprises that may generate emissions of hazardous substances apply for discharge permits, emission limit values will be determined on the basis of case-by-case assessments. As a general rule, strict limits are set for emissions of priority hazardous substances, regardless of the recipient of the release. Most enterprises in this category are subject to the EU Directive concerning integrated pollution prevention and control (the IPPC Directive).

The Norwegian Pollution Regulations regulate emissions and discharges from crematoriums. The provisions set rules for incineration, emissions to air and discharge to water, registration, measurements and reporting for crematoriums. The unofficial translation of the Norwegian Pollution Regulations you will find on the Norwegian Climate and Pollution Agency's website: [http://www.klif.no/artikkel\\_34963.aspx](http://www.klif.no/artikkel_34963.aspx). The Pollution Regulations also have provisions concerning discharges of waste water from dental clinics. The dental clinics must have a filter device for collecting amalgam and the filter devices have to be certified to retain 95% of the amalgam.

The emissions of mercury in Norway have been reduced by approximately 60 % since 1995, and 80 % since 1985.

The reports "Mercury substitution priority working list. An input to global considerations on mercury management" (TemaNord 2007:541) and "Socio-economic costs of continuing the status-quo of mercury pollution" (TemaNord 2008:580) issued by the Nordic Council of Ministers should also be made available to the INC. We understand that these reports are already received by the Secretariat.

Best regards,

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# **“Impact of a General Ban on Mercury in Products”**

**The Norwegian Pollution Control Authority  
(Statens forurensningstilsyn, SFT)**

**December 2006**

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## Summary

The action plan for reducing discharges of mercury has a general ban on mercury in products as one of its most important measures.

The Norwegian Pollution Control Authority (SFT) has assessed the consequences of introducing a general ban on the use of mercury and mercury compounds in products. Norway has regulations for the use of mercury, for instance in thermometers, electrical and electronic equipment (EE equipment), batteries and components in vehicles.

SFT has identified areas of use in which a general ban can be introduced without major problems and areas of use in which there will be a need for time-limited or permanent exemptions from a general ban. The proposed exemptions are based on a need to develop or standardise alternatives or allow the necessary time to invest in new equipment for both financial and production-related reasons.

Mercury is one of the most hazardous substances, imposing a threat to the environment and human health both in Norway as well as on a global basis. Mercury and various mercury compounds are extremely toxic to people and animals. The nervous system of fetuses and children are particularly vulnerable to adverse effects caused by mercury. Mercury is not degradable and accumulates in the food chain. Comprehensive dietary advisories concerning freshwater fish in Norway serve to emphasise the challenges we are facing. A number of measures have been taken to reduce the discharges, which include discharges from industrial enterprises, crematoria and municipal waste water, and mercury has been prohibited in thermometers. Environmental discharges of mercury from products can occur when they are used as well as if they end up in the environment. Even though the long-range pollutants are estimated to be more than twice as much as the national discharges, a general ban on the use of mercury in products will decrease the effects on the environment and on humans via the environment. Discharges from products comprise approximately 20 % of the total discharges in Norway.

The most important areas of use of mercury in products are in amalgam fillings, electrical and electronic equipment, special light sources, measuring devices and analysis chemicals. The largest quantities are used in amalgam fillings and light sources.

In 1991, the Norwegian Directorate for Health and Social Affairs introduced guidelines to reduce the use of amalgam fillings as a dental restoration material. The new guideline from 2003 state that filling materials other than amalgam, must be considered as the first choice for dental fillings. The consumption of dental amalgam has fallen by approximately 85 % since 1990 and the material represents an ever-decreasing part of the treatment options offered. A prohibition on the use of mercury will ensure that the reduction we see in the use of amalgam fillings continues and presumably be faster with a ban. The Norwegian Directorate for Health and Social Affairs stresses that exemptions for special patient groups will be needed.

By enhancing the removal efficiency of amalgam separators, it will also be possible to reduce discharges of mercury into the environment.

SFT emphasises that the reasons for proposing a prohibition on the use of mercury, including amalgam fillings, are based on the harmful effects of discharges of mercury into the environment. According to the Adverse Reaction Unit of Dental Biomaterials

(Bivirkningsgruppen, 2004), a ban on amalgam as a dental filling material on account of the health risk of patients could not be justified on the basis of the available observed side effects.

The Norwegian Product Regulations prohibit the use of mercury in new electrical and electronic equipment from 1 July 2006 with certain exemptions such as in fluorescent tubes and energy-saving bulbs. Using the current technology, they have to contain a certain quantity of mercury. Due to technical reasons and EU regulations, it is problematic to prohibit mercury in these products. Most EE equipment is imported into Norway. An important measure to prevent such products from ending up in the environment is to have collection facilities for this type of waste.

Mercury is still used in some measuring devices. In many cases, there are alternative measuring devices without mercury and there will not be a need for exemptions. These instruments have long lives and do not normally lead to discharges into the environment. Mercury from this area of use will be delivered to reception stations for hazardous waste.

Mercury is used as an analysis chemical and contributes just below 10 % of the discharges into water from equipment. Mercury is often precipitated as chlorides or sulphides and is delivered to reception stations for hazardous waste. For some analysis methods, there will be a need for a time-limited exemption from the ban in order to develop alternatives.

SFT does not have a complete cost overview for all areas of use. Nevertheless, based on the information obtained, SFT assesses that the introduction of the proposed regulations will probably not entail significant socioeconomic costs. However, this assumes that permanent/time-limited exemptions are granted and the prohibition will not result in an increase in the replacement of amalgam fillings. It is difficult to put into precise figures the reduction in discharges of mercury we will achieve with a ban in addition to the extensive restrictions that have already been introduced for mercury. Mercury is on the list of priority substances in Norway and is covered by Report to the Storting (White Paper) No. 21 (2004-2005). The objective for the use of mercury is to be reduced significantly before 2010. A prohibition of mercury in products would contribute to this goal being attained. Section 5 in this document provides an overall assessment of the benefits and costs of such a measure.

The Norwegian Directorate for Health and Social Affairs points out to SFT that, even if no adverse effects to health from amalgam fillings in living teeth can be demonstrated, there may be people who will feel uncertain if there is a prohibition and will want to replace well-functioning fillings.

The reasons for introducing a national prohibition on the use of mercury in products are based on an assessment of risk for the environment from the sources that exist in Norway. It is products containing mercury that may end up in the environment which specifically pose a risk. A general ban would prevent products from containing mercury when being produced or imported. Introduce a general prohibition on the use of mercury in products may influence other countries and international agreements towards stricter regulation of mercury.

# 1. Background

A national action plan to reduce discharges of mercury was presented by the Norwegian Ministry of the Environment in April 2005. A progress report for the action plan was sent to the Ministry of the Environment in May 2006. The environmental authorities want to reinforce initiatives against mercury and implement a number of measures to stop discharges of mercury as far as possible, both nationally and internationally. Mercury is one of the most hazardous substances and poses a threat to the environment and human health. Mercury contamination in Norway is caused both by national discharges and long-range pollution from other parts of the world.

Mercury discharges are increasing around the world. Action plans to reduce these discharges have been adopted by both the UN and the EU. In our national action plan, the focus is on ten important measures to reduce national discharges and contribute to a reduction in discharges in a global context. A prohibition of mercury in products is one of these measures.

Norway has ambitious national objectives for reducing mercury discharges, cf. the action plan. In 2003, national discharges were reduced by approximately 60 % in relation to 1995 as a consequence of several measures, among others a ban on thermometers containing mercury and a ban on mercury in batteries. The substitution principle and the precautionary principle are also the basis of the work to phase out the use of hazardous substances.

Our assessments are based on information obtained from relevant authorities, industries and institutes in Norway and a report from the Swedish Chemicals Agency (KemI, 2004): "Mercury - Investigation of a General Ban".

## Assessment of Risk

Mercury is one of the most hazardous substances imposing a threat to the environment and human health both in Norway as well as on a global basis. Mercury and various mercury compounds are extremely toxic to people and animals. The nervous system of foetuses and children are particularly vulnerable to adverse effects caused by mercury. Mercury is not degradable and accumulates in the food chain.

The health-related and environmental problems connected with mercury are mainly due to the bacteriological transformation of inorganic mercury to the very toxic compound *methylmercury*. This transformation occurs in aquatic systems, which causes methylmercury to be found especially in fish. The majority of this mercury is bound to the flesh of the fish, i.e. the part of the fish that we eat. In Norway, high values of methylmercury in some species of fish have led to dietary advisories from the authorities. Large freshwater predatory fish (piscivorous brown trout, arctic charr, perch and pike) should not be eaten more than once a month and pregnant and nursing mothers should totally avoid such fish. In marine areas the levels are lower, apart from fish in some fjords with known local mercury discharges. Studies from inner Oslo Fjord show, however, increasing levels of mercury in cod. The incidence of mercury in Norwegian drinking water sources is quite low, and the exposure to mercury via drinking water is, according to the Norwegian Institute of Public Health, considered to be of no significance.

A number of measures have been taken to reduce the discharges, which include discharges from industrial enterprises, crematoria and municipal waste water, and mercury has been prohibited in thermometers. Environmental discharges of mercury from products can occur when they are used as well as if they end up out in the environment. Even though the quantities of the long range pollution of mercury are estimated to be more than twice as much as the national discharges, a general ban on the use of mercury in products will decrease the effects on the environment and on humans via the environment.

The total discharges of mercury to the air, soil and water from Norwegian sources was approximately 1000 kg in 2003. Over 80 % of the Norwegian discharges go into the air, while the rest goes to the soil (14 %)<sup>1</sup> and water (6 %). In an international context, the Norwegian discharges are relatively small. Discharges from products comprise approximately 20 % of the total discharges in Norway.

The scope of the mercury pollution in the Arctic (the northern areas) is increasing. Mercury pollution currently comprises a risk for animals and humans in Arctic areas. For people in the Arctic, mercury poses a particular risk to health because fish and aquatic mammals comprise such a large part of the diet of some sections of the population. The special conditions in the Arctic make the area particularly vulnerable.

The EU has done a risk assessment of mercury in products (Risks to Health and the Environment Related to the Use of Mercury Products, RPA Final report: J372/Mercury). This risk assessment was performed with respect to the EU's programme for existing substances (Directive 793/93/EEC) with the use of the EUSES model. In 2003, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) stated that the EUSES model was unsuitable for risk assessments of metals, however the hazardous properties of mercury have been known for many years.

Mercury has also been reported on in the UN's environmental programme (Global Mercury Assessment, UNEP 2002). The conclusion of this report was that mercury has such large negative effects that further international measures should be undertaken to reduce the risks to human health and the environment. At the ministerial level it was decided that measures should be initiated as soon as possible to reduce discharges on local, regional and global levels.

Our national action plan for reducing discharges of mercury has a ban on the use of mercury in products as one of its important measures. The justification for introducing a national ban on mercury and mercury compounds in products is based upon an overall impact of the risk to the environment from the sources that exist in Norway.

## 2. Definitions and Limitations

- The impact of consequences covers products in which mercury is added intentionally. Mercury that occurs naturally, for example in coal, ore and ore concentrate, is thus not assessed here.

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<sup>1</sup> Of this, approximately 80 % is attributable to graveyards due to amalgam fillings in the teeth of deceased persons.

- Areas of use that are already regulated are not assessed in terms of alternatives and costs.
- The impact of consequences has focused on the most important regulations which relate to mercury in products and which lie within SFT's area of responsibility.

### 3. EU Mercury Regulations

There are a number of regulations that cover mercury. There are 15 EU Directives concerning the use of mercury in products, see below. The relevant regulations will be discussed in further detail under the individual areas of use in sections 4.1 – 4.4.

#### **The following Directives are administered by SFT:**

- Batteries Directives 91/157/EEC, 93/86/EEC and 98/101/EC are implemented in the Norwegian Product Regulations. A new Batteries Directive was adopted by the EU Parliament in September 2006.
- Directive on Risk Reduction Strategy. Directive 76/769/EEC is implemented in the Norwegian Product Regulations.
- Directive for electrical and electronic equipment. Directive 2002/95/EC (the RoHS Directive) is implemented in the Norwegian Product Regulations.
- Directive for electrical and electronic equipment as waste. Directive 2002/96/EC (the WEEE Directive) is implemented in the Norwegian Waste Regulations and Product Regulations.
- Directive for end-of-life vehicles. Directive 2000/53/EC is implemented in the Norwegian Waste Regulations.
- Biocide Directive. Directive 98/8/EC is implemented in the Norwegian Biocide Regulations.
- Regulations on export and import. Regulation (EC) No. 304/2003 concerning the export and import of dangerous substances.
- Packaging Directive. Directive 94/62/EC (apart from packaging for food products).

#### **Other Directives that are administered by other authorities:**

##### The Norwegian Directorate for Health and Social Affairs<sup>2</sup>

- Active Implantable Medical Devices Directive. Directive 90/385/EEC.
- Medical Devices Directive. Directive 93/42/EEC.
- In Vitro Diagnostic Directive. Directive 98/79/EC.

##### The Norwegian Medicines Agency

- Directives and Regulations concerning medicines. Regulation (EEC) No. 2309/93.

##### The Norwegian Food Safety Authority

- Packaging Directive. Directive 94/62/EC (covers packaging for food products).
- Cosmetics Directive. Directive 76/768/EEC.

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<sup>2</sup> The three directives below were implemented in the Administrative Regulations of 15 December 2005, No. 1690.

The Norwegian Directorate for Civil Defence and Emergency Planning (DSB) and SFT

- Toys Directive. Directive 88/378/EEC.

The Norwegian Directorate of Public Roads:

- Directive for type approval of motor vehicles. Directive 70/156/EEC.

Norway has an exemption for the Pesticides Directive in the EEA Agreement. Pesticides are regulated in the Norwegian Pesticides Regulations. These regulations are administered by the Norwegian Food Safety Authority.

Directives administered by other authorities will be affected if they do not have separate regulations in relation to mercury. SFT has been in contact with several of these authorities and they may express their opinions in connection with the hearing process.

The REACH regulatory framework for chemicals will include the Directive on Risk Reduction Strategy, which regulates, among other things, mercury in thermometers, batteries and vehicles. REACH will be able to include new areas of use. The proposal for REACH states that the member countries will be able to keep their national regulations for up to 6 years.

## 4. Areas of Use

The report “Hazardous Substances in Products” (Miljøgifter i produkter) provides consumption figures and discharge quantities for mercury in 2003. On the basis of this, relevant areas have been identified which have been studied in further detail in terms of the consequences of a general prohibition.

Table 4.1. *Consumption of mercury in products in 1995, 2002 and 2003.*

Product type	Quantity in kg, calculated as Hg		
	1995	2002	2003
Amalgam filling materials	840	230	139
Batteries	215	5 *	5 *
Light sources	130	164	160
Thermometers	90	0	0
Analysis chemicals	40	30	30
Miscellaneous meters	55	40	40
Switches and relays	5	0	0
Pesticides	0	0	0
Medicines	0	0	0
Mineral fertiliser, lime		1	1

\* More recent data on button cell batteries than in “Hazardous Substances in Products”.

Since the use of mercury has been prohibited in thermometers and gradually phased out in most batteries, four major areas of use remain. This is also reflected in the discharge figures in the table below.

Table 4.2. *Discharges of mercury from products in 2003.*

Product type	Sales, kg Hg	Discharge into the air, kg Hg	Discharge into water, kg Hg	Discharge into the soil, kg Hg	Waste, kg Hg
Amalgam filling materials	139	57	16.4	137.4	703
Batteries	0			2 *	3 *
Light sources	160	32	9.6	6.4	112
Thermometers	0				
Analysis chemicals	30		3		27
Miscellaneous meters	40	14			26
Switches and relays	0				
Pesticides	0				
Medicines	0				
Mineral fertiliser, lime	1			1	

\* More recent data on button cell batteries than in “Hazardous Substances in Products”.

The total discharges into the environment are divided into discharges into the air, water and soil. The right-hand column with waste quantities is what is delivered to recipients of

hazardous waste and will thus be dealt with in an environmentally sound manner. Mercury in mineral fertiliser occurs naturally in lime.

#### **4.1 Dental Filling Materials (Amalgam)**

Approximately 140 kg of mercury are estimated to have been used in amalgam fillings in 2003. This is a reduction in consumption of approximately 40 % from 2002. The total discharges are estimated to 210 kg mercury. The discharge sources are discharge into the air from dental clinics and crematoria (57 kg), discharge into the soil in graveyards (137 kg) and discharge into water via municipal sewers and sludge (16 kg). Amalgam from amalgam separators containing approximately 700 kg mercury was delivered to reception stations for hazardous waste in 2003.

Amalgam is an alloy consisting of approximately 50 % mercury and other metals such as silver, tin and copper. Amalgam will leak mercury to a very low extent when placed in teeth.

Amalgam fillings have long lives. The quantity of amalgam in living teeth represents approximately 10 tonnes of mercury in Norway today. The population for those over forty to fifty years have amalgam fillings. As the fillings need to be replaced, they are replaced with crowns or people die, the quantity of mercury in living teeth will fall. It is estimated that a reduction in discharges will not be seen until after 2020.

#### **Regulations**

The discharge of mercury into the air from the largest crematoria is regulated in Norway. The regulations apply to crematoria established after 1 January 2003. For crematoria that existed before 1 January 2003, purification requirements apply from 1 January 2007. 67 kg of mercury was discharged into the air from crematoria in 2003. The number of cremations per annum varies from 10,000 to 14,000. 33 % of the bodies are cremated.

Waste water containing amalgam and waste containing amalgam from dental clinics are also regulated in Norway. A prohibition of discharges and a requirement to have an approved amalgam separator were introduced in 1995. This led to significant reductions in mercury discharges into municipal sewers. The reduction was 82 % from discharges of 350 kg per annum in 1995 to 60 kg per annum in 2003. There will be some discharge of mercury even after purification and regular emptying and inspection of the amalgam separators that are necessary to achieve a 95 % degree of purification. All waste and sludge containing amalgam must be delivered to reception stations for hazardous waste.

There is no regulation of the use of amalgam in Norway or the EU. The county survey conducted by the Directorate for Health and Social Affairs in 2002 formed the basis for “A National Clinical Guideline for the Use of Dental Filling Materials”, which was published in 2003. These guidelines read that “*Amalgam must usually not be the first choice for any indication of filling therapy*” and “*Use of amalgam must be limited as far as possible out of consideration for the environment and potential damage to health*”. The result so far is that the use of amalgam has decreased on account of the strict provisions in the guidelines. The use of amalgam must be justified in the patient records and the patient must have given his or her consent.

### **Brief Historical Development**

There has been a large reduction in the consumption of amalgam. Composites (plastic) were introduced in the 1970s. Initially, they were only used in teeth without chewing pressure. Today's composites have better technical and chemical properties and can also be used in molars. The reduction in amalgam use is the result of an improvement in dental health, which largely is the result of fluoride toothpaste becoming available in 1971. As dental health improved, the criteria for filling therapy were changed. The holes that required filling therapy were smaller.

The phase out of amalgam accelerated after guidelines for dental filling therapy were introduced in 1991. The Directorate of Health and Social Affairs recommended, in these guidelines, that extensive amalgam therapy should be avoided in pregnant women for reasons of general prevention. The guidelines also read: "As a contribution to reducing the environmental impact of mercury, the Directorate recommends that the use of amalgam be reduced successively".

### **Alternative Products**

Alternatives to amalgam exist today. A survey conducted by the Directorate for Health and Social Affairs in 2002 revealed that dentists now prefer to use composite as a filling material. Compared to the results of the Norwegian Board of Health's survey of amalgam used in children and young people in 1995, the survey in 2002 shows a reduction of around 90 % in the proportion of amalgam fillings in this age group.

New, more durable tooth-coloured materials are marketed. Aesthetic dental treatment has gradually become a concept that excludes the use of amalgam. The problem of possible adverse effects, patients' increased interest in filling materials and patients' preferences have probably also accelerated the development away from amalgam, according to the Directorate for Health and Social Affairs.

### **Properties and Adverse Effects of the Various Dental Filling Materials**

All materials used in dental restoration involve a certain risk of adverse effects. The Adverse Reaction Unit of Dental Biomaterials (Bivirkningsgruppen for odontologiske biomaterialer) was established on 1 January 1993. In the period 1994-2005, the Unit was referred 688 patients with suspected adverse effects from dental materials, 512 of whom on account of amalgam. Of these 688 patients, 76 patients were recommended to replace their fillings, but this applied also to fillings based on other materials (Annual Report 2004). In such selected material as this (patients referred with suspected adverse effects), there are few demonstrable adverse effects of amalgam as a filling material in Norwegian patients. According to the Unit, a prohibition of amalgam as a dental filling material on account of the risk of injuring the health of patients could not be justified on the basis of the available observed adverse effects.

Materials that contain acrylates may emit unreacted components right after the dental filling has hardened. Apart from allergic reactions, there is little reliable information so far on possible harmful effects of these substances. Particular attention has been paid to bisphenol A and/or bisphenol A derivatives. These substances are endocrine disrupters and it has been shown that they have an effect resembling that of oestrogen. However, the quantities of such substances emitted are small. At present we have little knowledge of whether exposure to low doses of bisphenol A can result in adverse health-related effects. The Adverse Reaction Unit will keep itself updated on possible negative effects of the different dental filling materials.

However, mercury is presumably an occupational health problem for the dental personnel who work with the material, in addition to being an environmental problem. When old fillings are removed, vacuum suction and water-cooling should be used to avoid unnecessary exposure of both the patient and the personnel to hazardous substances. A separate publication has been prepared by the Directorate for Health and Social Affairs addressing in detail issues concerning health, the environment and safety in the Norwegian Public Dental Service.

### **Treatment-related Consequences**

The Directorate for Health and Social Affairs considers that a ban will not lead to any treatment-related consequences for the most common dental treatment performed, as amalgam is little used. A prohibition would increase attention to amalgam as a filling material for the groups in the population who were treated in the 1970s and 1980s, when the material was used as the first choice in dental restoration. SFT emphasise that the reasons to prohibit the use of mercury, including amalgam fillings, are based on the harmful effects of discharges of mercury into the environment and not a health-related impact of having amalgam fillings in the mouth.

Treatment under general anaesthesia may be an area in which amalgam is still used. The reason is treatment-related problems making durable composite fillings. It is difficult to keep it sufficiently dry when treating a patient who is under general anaesthesia, which is necessary when using composites. It also takes longer time to use filling material other than amalgam. However, these problems should be possible to deal with, and the use of amalgam can be replaced with other alternatives in most cases today.

### **Cost Assessment**

Some groups of the population have the costs of their dental treatment covered in full or in part by the State. These include children and young people, the mentally disabled and the elderly in institutions. Treatment is provided by the county municipal dental service or by a private dentist who has an agreement with the county municipality. The Ministry of Health and Care Services (HOD) sets rates for groups of adults who have their expenses covered in full or in part by national insurance benefits. Apart from this, dental services are not state-financed or subject to price regulations in Norway.

The prices for dental services are considered by many to be very high. According to the Norwegian Competition Authority (3/2005), one of the reasons for this is probably that there are insufficient dentists in Norway, especially outside densely populated areas. Most dental customers do not search for the cheapest dentists. When they purchase dental services, they are relatively unconcerned about price and therefore have a high willingness to pay.

The freedom to set prices means that it is not possible to establish accurately how much it will cost the patient to use an alternative dental filling material to amalgam. SFT has used the rates from the Norwegian Ministry of Health and Care Services for public subsidy for dental treatment to calculate an estimate of the price difference for the patient between the different dental filling materials.

For preparation and filling, the price difference between amalgam and composite is NOK 80.00 for one surface and NOK 235.00 for two surfaces. It is not possible to use plastic for

large fillings. This will mean a greater price difference than that stated above if it is necessary to use gold as an alternative filling material to amalgam.

The cost of the material for a filling, regardless of the material, represents approximately 5-10 % of the total treatment costs. Nearly  $\frac{3}{4}$  of the costs are salary costs. The purchase costs for composite material, among others, are higher than for amalgam and the increased demand for alternative filling materials has not led to a lower purchase price from suppliers. The Directorate for Health and Social Affairs' guidelines state that, over a period of ten years, it is probable that the alternatives to amalgam will mean higher maintenance costs because they are less durable.

For dental clinics that perform treatment under general anaesthesia and currently do not have the necessary equipment to do this with composite fillings, a prohibition of amalgam will mean they will have to invest in new equipment. However, these costs are low, NOK 5,000 - 15,000. Administrative costs are necessary to follow up on the prohibition of the use and import of amalgam. The use and thus the import of amalgam are generally low. Dentists have voluntarily switched to using alternative filling materials. Some follow-up of the prohibition will be necessary. But there is reason to assume that the administrative costs will be low.

### **Socioeconomic Impact**

The use of amalgam has been greatly reduced on a voluntarily basis in recent years, among other things because of the strong provisions in the guidelines issued by the Directorate for Health and Social Affairs. There is reason to assume that this trend will continue regardless of a prohibition. However, a prohibition would ensure a continuation of the reduction of the use. It is difficult to say how much a prohibition of the use of amalgam would reduce the discharges. The majority of the amalgam used today will, in the long term, be collected and not end up as discharge.

This makes it difficult to quantify the benefit of the prohibition on the use of amalgam which make it difficult to to quantify the benefits of a ban. However, a prohibition of amalgam would probably lead to a faster phasing out of amalgam as a filling material.

The costs of a prohibition are considered to be low, provided that the prohibition will not result in an increase in the replacement of amalgam fillings since the use of amalgam already is strongly reduced. The costs are thus low, because most patients would have selected a different filling material than amalgam. Overall, there is reason to assume that the benefit of a prohibition will exceed the cost.

### **Allocative effects**

Patients who get amalgam as a filling material will experience increased costs when they get alternative filling materials. Most patients will have to meet this cost themselves. Although the dental health of the majority of the population is good, there will be great individual differences. Poor dental health will often affect weak groups in society who neglect treatment on account of the high costs. For some major restoration work, the alternative to relatively inexpensive amalgam fillings will be expensive treatment in the form of crowns.

All dental filling material is imported into Norway. The importers have experienced a large decrease in the importation of amalgam in recent years. At the same time, this will increase the need to import alternative filling materials. The costs of a prohibition of amalgam are, therefore, estimated to be low for the importers.

### **Need for Certain Exemptions from a General Prohibition on the Use of Amalgam**

In a survey conducted by the Directorate for Health and Social Affairs, dentists in Norway have identified the need for certain exemptions from the general prohibition. Brief summary:

1. From a professional point of view, there should be an exemption for dental treatment under general anaesthesia on account of the time required, complicated working conditions, the number of sessions and the length of the sessions, which indicate an exemption.
2. The Adverse Reaction Unit considers that people who are allergic to ingredients in plastic fillings will be subject to very high costs if they cannot get amalgam fillings. However, this can be solved with other materials that are a great deal more expensive. Exemption pending refund schemes, cf. a suggestion from the Norwegian Dental Association (Den norske tannlegeforening).
3. The Norwegian Dental Association considers that patients with dryness of the mouth and patients with special needs for treatment require an exemption from the prohibition.

The Directorate for Health and Social Affairs proposes to introduce a time-limited exemption for 1 and 2 above. Patients under 3 who are difficult to treat are often treated under general anaesthesia and are covered by 1.

**Conclusion:** *A time-limited exemption from the general prohibition up through and including 31 December 2010 is proposed for patients:*

- 1) *who require treatment under general anaesthesia, and*
- 2) *who are allergic to ingredients in plastic fillings.*

#### **Remarks:**

It is proposed that the following be mentioned under the comments for section 2-6 of the regulations:

*The dental treatments must be in line with the "A National Clinical Guideline for the Use of Dental Filling Materials" prepared by the Norwegian Directorate for Health and Social Affairs in 2003 as amended.*

## **4.2 Electrical and Electronic Equipment**

An estimated 160 kg of mercury was used in light sources and 48 kg of mercury discharged from light sources in 2003, according to “Hazardous Substances in Products”. Mercury is used in fluorescent tubes and energy-saving bulbs. Mercury was previously also used in various electrical switches and some such switches are still in use. They are removed from scrapped electrical equipment that is delivered as electrical and electronic waste (EE waste).

### **Regulations**

The RoHS Directive (Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment) prohibits mercury, cadmium, lead, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE) in electrical and electronic equipment (EE equipment). These provisions are implemented in sections 3-17 to 3-19 in the Norwegian Product Regulations, plus Appendix V, which entered into force on 1 July 2006. There is an exemption for fluorescent tubes and energy-saving bulbs.

The WEEE Directive (Directive 2002/96/EC on waste from electrical and electronic equipment) regulates EE waste. Norway has had regulations on scrapped EE products since 1998. These regulations and the new provisions in the Directive are in Chapter 1 of the Norwegian Waste Regulations, which deals with scrapped EE equipment. The Norwegian regulations are more far-reaching than the WEEE Directive and cover, among other things, EE equipment from industrial use.

Currently, the RoHS Directive contains exemptions for 2 of the product categories that are included in WEEE. These are medical equipment (category 8) and monitoring and regulation devices (category 9). According to the RoHS Directive, the EU Commission must assess whether these categories will be covered by the RoHS Directive and when. Until the Commission has completed its impact, these product categories will be exempted from RoHS and thus will be exempted from the Norwegian general prohibition of mercury. This means that the use of mercury in these product categories will be allowed until further notice.

With respect to medical devices, there are three directives (90/385/EEC, 93/42/EEC, 98/79/EC) that are administered by the Directorate for Health and Social Affairs. These directives concern the technical and functional requirements for the equipment. Until further notice, the possible use of mercury in such equipment is exempted due to the RoHS Directive. These exemptions follow from their demarcation from the body of regulations for EE equipment in the proposal for amending the regulations.

### **Light Sources**

The RoHS Directive and the Norwegian Product Regulations contain exemptions for the use of mercury in light sources. The mercury content must be under certain quantities, depending on the type of light source. The new limit values are lower than those for the fluorescent tubes that are sold today. However, according to the industry, it is fully possible to meet the new requirements in the Directive.

The fluorescent tubes must contain a certain quantity of mercury to enable them to work. The average quantity of mercury in fluorescent tubes has fallen in recent years, but it cannot fall to zero. Alternative light sources to fluorescent tubes and energy-saving bulbs (which are based

on fluorescent tubes) are standard filament-based light bulbs. However, the energy consumption of standard light bulbs is much higher and the environmental impact from energy production must also be taken into consideration. Halogen bulbs are a variant of filament bulbs. They were first used for vehicle lights but are now also used for indoor and outdoor lighting, especially in spotlights. They use less energy than conventional filament bulbs. The orange sodium vapour lamps used for street lighting also have low energy consumption but they are poorly suited to many purposes on account of the colour of the light.

There are great expectations that light-emitting diodes, LED, will become the light source of the future. They use a fraction of the energy of a filament bulb with the same luminous efficiency and they last for over 10,000 hours. They have been used for many years as indicator lamps on electrical equipment and, in recent years, they have started to be used in bicycle lights, torches and traffic lights. It must be expected that they will gradually be used as spotlights. It is difficult to say whether they can replace fluorescent tubes.

A new area for the use of mercury is in light sources in TV and PC flat screens. Sales of flat screens in Norway in 2005 are estimated by the industry to be 180,000 units. A flat screen contains 3-4 mg mercury and the total quantity sold will be approximately 0.7 kg mercury per annum, based on the estimated sales figures from 2005. The quantity of mercury in a screen is approximately half that in a standard fluorescent tube. This represents a small quantity compared with the 160 kg per annum used in light sources overall. However, it may increase in the future as the old TVs and PC screens are replaced. The EU has assessed such light sources under the RoHS Directive and granted them an exemption. However, they are covered by the provisions in the Norwegian Waste Regulations on EE waste. It must be expected that a large proportion of such screens will be delivered as EE waste when they are scrapped. Most consumers are aware that EE equipment must be delivered to reception stations for hazardous waste.

**Conclusion:** *Light sources are regulated as far as is technically feasible today. Under the general prohibition, reference will be made to Sections 3-17 to 3-19 of the Norwegian Product Regulations and Appendix V for electrical and electronic equipment.*

### **Switches and Relays**

Mercury has been used and is still used in switches and relays to regulate or switch on/off current in thermostats, rocker switches, level switches, signal systems, high-power switches, traffic lights, etc. In these areas of use, there has been a gradual shift towards electronic components as there has been a drive in the industry itself to phase out mercury.

This area of use has not previously been regulated in Norway. Sweden has a time-limited exemption in previous regulations from 1998. They have a maximum limit for the mercury content for contacts and relays to the end of 2007. There are also exemptions for switches for ABS brakes and airbags to the end of 2006. There are alternatives to mercury in these products. Since the prohibition was introduced in Sweden in 1998, there have been virtually no applications for exemptions. By far the most areas of use fall under the provisions of the Norwegian Product Regulations concerning EE equipment, and a general ban would also cover possible areas of use that are not covered by the Norwegian Product Regulations.

Switches and relays that contain mercury have, according to the industry, nearly been phased out in Norway, and the costs of a ban would therefore probably be low. To the extent that they are used, they will be collected when being disposed of and be treated as hazardous waste. A

ban would thus result to only a small extent in a reduction of discharges of mercury. However, it would prevent switches and relays containing mercury from being installed.

**Conclusion:** *No exemptions are proposed from the general prohibition for switches and relays.*

### **Contact Material in Welding Equipment**

Ventilation pipes and tin cans are made using welding machines. Older machines have mercury inside the welding electrodes (the wheels) to create good electrical contact. The mercury is completely enclosed in the wheels and does not escape. The wheels with mercury are replaced at intervals of 2-3 years. The quantity of mercury is a little less than 0.5 kg per year. In Norway, 2 companies perform such welding. The machines have a life of 30 years and new machines do not use mercury in the wheels.

A ban would involve the companies having to replace their machines or to convert them, something that could result in significant expenses. At the same time, a ban would not result in any reductions in discharges of mercury since the mercury does not escape and it is treated as hazardous waste. On this basis SFT recommends that a time-limited exemption be granted in order to give the companies time to make new investments.

**Conclusion:** *A time-limited exemption from the general ban is proposed for contact material in welding equipment until 31/12/2010.*

### **Transmitters for Predators**

According to information from the Norwegian Directorate for Nature Management (DN), alternatives have not at present been evaluated for transmitters containing mercury. It thus is not possible to provide any impact of the benefits and costs of a ban in this area. In its impact study, the Swedish Chemicals Agency arrived at the conclusion that there are not any adequate alternatives on the market. Our impact is thus that there is a need for a time-limited exemption from the ban in order to develop alternatives.

**Conclusion:** *A time-limited exemption from the general ban is proposed for transmitters for predators until 31/12/2010.*

### **Components in Vehicles**

Section 3-15 and Appendix III of the Norwegian Product Regulations concern a ban on importing vehicles produced after 1 July 2003 that contain components including mercury (apart from light bulbs and instrument lighting). Producing such vehicles is also prohibited as at the same date. This is the implementation of EU Directive 2000/53 concerning scrapped vehicles.

Section 4-7 of the Norwegian Waste Regulations, concerning end-of-life vehicles states that anyone who operates a processing plant for scrapped vehicles must remove components and materials that are labelled or otherwise made identifiable in Section 3-15 of the Norwegian Product Regulations. This provision applies from 1 July 2004.

Good systems have been established in Norway to sort out environmentally hazardous components in vehicles. The level of sorting is high, approximately 95 %, and the waste is delivered to reception stations for hazardous waste.

**Conclusion:** *Components in vehicles are regulated as far as is technically feasible today. Under the general ban, reference will be made to Section 3-15 of the Norwegian Product Regulations, and to Appendix III.*

### **Electrical and Electronic Waste**

Since 1999, Norway has had provisions on how producers, importers and dealers must deal with EE waste. The system works very well and over 90 % of waste is delivered to reception stations. According to the Norwegian Product Regulations, producers must provide information on dismantling their EE equipment, with a description of hazardous components and their location. The information must be as detailed as required to ensure environmentally sound processing of the product.

### **4.3 Batteries**

No consumption and discharge of mercury for batteries were estimated in “Hazardous Substances in Products” for 2003. However, some small quantities are still permitted in button cell batteries. The importers of batteries estimate that button cell batteries are imported every year containing a total of 5 kg mercury.

Sections 3-13 and 3-14, plus Appendices I and II, of the Norwegian Product Regulations regulate the labelling of batteries containing mercury and ban the production, importation, exportation or sale of batteries that contain more than 5 ppm mercury, except for button cell batteries that contain less than 2 % by weight mercury. The level of collection for such batteries is very low. The EU has adopted a new Batteries Directive that imposes the collection and processing of all types of battery. This is expected to result in a larger proportion of button cell batteries containing mercury being collected in Norway.

The heavy metal content of batteries has been regulated in Norway for nearly 20 years. The estimated consumption of mercury in batteries was 215 kg in 1995. Consumption is now down to 5 kg mercury. There has been a gradual reduction in the minimum permitted quantity of mercury in line with what has been technically feasible. Discharges to the environment from batteries are thus negligible in a wider context.

**Conclusion:** *Batteries are regulated as far as is technically feasible today. Under the general ban, reference will be made to Sections 3-13 to 3-14 of the Norwegian Product Regulations, and to Appendices I and II.*

### **4.4 Measuring Devices and Analyses**

An estimated 40 kg of mercury is used per annum in measuring devices and 14 kg discharged from them. An estimated 30 kg of mercury is used per annum in analysis chemicals and 3 kg discharged from them. The remaining quantities are delivered to reception stations for hazardous waste. The consumption figures also include use of mercury in chemical analyses. Miscellaneous meters includes lamps and electrodes in analysis devices, manometers, gyroscopes and gas flow meters and other electrical and electronic equipment.

The beneficial effects associated with a proposed ban on mercury in measuring devices and analysis chemicals will be a reduction in discharges of mercury by 17 kg per annum. This is based on estimated discharges of mercury in “Hazardous Substances in Products for 2003”.

For analysis chemicals, there are some areas of use in which there are no alternatives and areas in which use is already regulated via national or EU provisions. This applies for the use of mercury in analyses, for example as a reagent. There will therefore be a need for a time-limited exemption from the ban in order to develop alternatives. With respect to the analysis of mercury content itself, there must be a standard test containing mercury in order to be able to make comparisons. A permanent exemption is proposed for this type of analysis.

The Norwegian Institute for Water Research (NIVA), the Norwegian Institute of Public Health (FHI) and Norwegian Accreditation (NA) have given comments on the use, consequences of a ban, alternatives, etc. These bodies regard the situation in Norway as very similar to that in Sweden and have commented on some of the areas of use mentioned in KemI's report.

The Norwegian Institute of Public Health (FHI) states that they are not aware, within their specialist area, that mercury is used in analytical contexts. There are some older devices that use mercury (cell counters, water baths, thermometers, switches and relays). These type of instruments is presumably little used today. Most of those that are used today should, relatively easily, be modifiable or replaceable (for example, water baths, etc.). FHI supports the Swedish proposals for a ban and transitional periods.

Norwegian Accreditation (NA) has assessed the KemI report and comments that they have done thorough work. According to NA, there are alternative measuring instruments that do not contain mercury. NA has not been able to find any measuring devices that requires a time-limited exemption.

## **Measuring Devices**

The EU has evaluated restrictions for certain measurement devices that contain mercury. A proposal exists in the Restrictions on Marketing and Use Directive (Directive 76/769/EEC). This involves a ban on the use of mercury in 1) fever thermometers and 2) in other measurement instruments for private use, for example manometers, barometers, sphygmomanometers and thermometers other than fever thermometers. In general research, development and analysis purposes are exempted from the Restrictions on Marketing and Use Directive, cf. article 2. Corresponding demarcations of the applicability appear in section 1-2 of the Norwegian Product Regulations. Under this provision, products for analysis and research purposes are exempted from the regulations, unless specifically stated otherwise in the individual provisions.

Norway has had a prohibition on the sale of mercury thermometers since 1 October 1998. Use of existing thermometers has been allowed. The regulations had an exemption up to 1 January 2001 for thermometers for occupational use for meteorological, hydrological and oceanographical measurements and for control measurements and calibrations in laboratories.

The proposed regulations in the EU will limit the ban on thermometers to only applying to fever thermometers for occupational use. The applicable Norwegian prohibition in section 2-6 of the Norwegian Product Regulations comprise all types of thermometers.

The proposal for a general ban expands the Norwegian existing regulations to include "other measurement devices" in line with the EU's proposal. However, we ought to be able to go

further by including occupational use in the ban. This has been supported by the research communities we have been in contact with, who are of the opinion that there are no great technical or financial barriers to implementing a ban in this area.

### **Thermometers**

Section 2-6 of the Norwegian Product Regulations regulates mercury and mercury compounds for various purposes and states that it is prohibited to produce, import, export and sell mercury thermometers, including for analysis and research purposes. Some exemptions have been granted from this prohibition after the exemption was terminated on 1 January 2001. The prohibition has led to a large reduction in the consumption of mercury in thermometers. In 1995, there was an estimated consumption of 90 kg mercury. A major collection campaign in 1998 led to the collection of the majority of mercury thermometers that were in use in private homes.

For some areas of use, there are problems finding suitable alternatives to mercury thermometers. These include flashpoint analyses, for which the standard requires mercury thermometers. Electronic data loggers can be used in autoclaves, but there can be problems with high pressure and temperature.

Many laboratories have to test their thermometers against a calibration thermometer at regular intervals. There are electronic calibration thermometers but they are very expensive and they must be sent in frequently for inspection or certification by special companies.

***Conclusion:** Our previous ban on the use of mercury in thermometers, including for use for analysis and research purposes, will be maintained.*

### **Manometers, Barometers and Sphygmanometers**

Mercury manometers are used for particle counting, for measurement of biological oxygen demand (respirometric method) and for degradability tests. This type of equipment is used by several laboratories in Norway. Alternatives without mercury are available on the market today, but presumably would be expensive to purchase brand new.

The use of mercury in barometers has already been replaced to a large extent. Good alternatives exist and a general ban would not have substantial consequences.

The use of mercury in sphygmanometers (blood pressure gauges) by the national public health service has ceased almost completely according to the Directorate for Health and Social Affairs. Mercury in blood pressure gauges has not previously been regulated in Norway. A general ban will presumably not have major consequences for the use of manometers and sphygmanometers.

***Conclusion:** No exemptions are proposed from the general ban for manometers, barometers and sphygmanometers. It is also proposed that the ban should also apply to the use of manometers, barometers and sphygmanometers for analysis and research purposes.*

### **Polarographs**

Mercury is used in a dripping or suspended mercury electrode for polarographs. Polarographs are instruments that measure current curves during the electrolysis of chemicals. Such instruments are used for special analyses. SFT is not aware of precisely what alternatives currently exist to the use of mercury electrodes in polarographs. Polarographs have however

already been banned in Sweden. The Swedish Chemicals Agency has proposed in its corresponding proposal for a general ban that there be a time-limited exemption for spare parts up through and including 2007. Contact with relevant environments in Norway has resulted in any stated need for a permanent exemption for polarographs. SFT is however proposing a time-limited exemption for polarographs.

**Conclusion:** *A time-limited exemption from the general ban is proposed for polarographs until 31/12/2010.*

## **Analyses**

### **Analysis of Chemical Oxygen Demand (COD)**

Mercury sulphate is used as the reagent in the analysis of chemical oxygen demand (COD) in samples containing chloride. This is a Norwegian Standard. This analysis is one of the major areas of use for mercury (approximately 25 %) for analysis chemicals.

The alternative is analysis of the total organic carbon (TOC). This will involve a major investment in the laboratories. The increased investment will, in the long term, be compensated for by lower operating costs and by the costs of delivering hazardous waste being eliminated.

SFT requires reporting of COD in accordance with the Norwegian Standard in discharges of process water from industry. Samples are taken for this analysis once a month. In the pulp and paper industry, daily measurements of COD are also taken with other methods that do not contain mercury (the Dr. Lange and HAKK methods).

It is a desire on the part of the industry itself to move away from analyses involving the use of mercury out of considerations for the working environment. Analysis methods that are utilised must be in accordance with the Norwegian Standards. If we consider an alternative method, the tests mentioned, must therefore be ring tested before they can be evaluated as a "new" Norwegian Standard for this analysis. I.e. multiple laboratories must perform the same test a number of times and the results must be checked to see whether they concur and are reproducible .

SFT proposes that the initiative be taken to carry out such a ring test and that one of the methods be selected as a new Norwegian Standard. Such a process would take some time and a time period of 3-4 years ought to be sufficient.

**Conclusion:** *A time-limited exemption from the general ban is proposed for analysis of COD with mercury until 31/12/2010.*

### **Analyses of Mercury**

There are requirements for analyses of mercury according to international standards in the regulations within several areas (food, medicines, medical diagnosis, etc.). To perform these analyses, it is necessary to measure against standards that contain mercury. A permanent exemption from the ban should be granted.

**Conclusion:** *A permanent exemption is proposed from the general ban for analyses of mercury.*

## **Other Areas**

### **Disinfection of Dialysis Devices**

The preservative thiomersal contains organic mercury compounds and has been used to disinfect dialysis devices in hospitals. Thiomersal is no longer used in Norway for disinfection.

***Conclusion:** No exemption is proposed from the general ban for the use of thiomersal for disinfection.*

### **Preservation of Vaccines**

The preservative thiomersal is also used in vaccines for hepatitis and influenza, among other things. There are very small quantities of thiomersal in these products. However, the amount will become large when there are epidemics. At present, there are alternatives to the use of thiomersal. These are being checked out by the pharmaceutical manufacturers. The marketing mechanism must be in place before thiomersal can be replaced with mercury-free preservatives. According to the Norwegian Medicines Agency such would be possible within 3-4 years.

***Conclusion:** A time-limited exemption from the general ban is proposed for the use of thiomersal as a preservative in vaccines until 31/12/2010.*

## 5. Overall Assessment of Benefits and Costs

SFT does not have a complete overview of the costs for all the areas of use. Nevertheless, based upon the information that SFT has obtained, it is our opinion that the introduction of the proposed regulations would not lead to significant economic costs. This is based upon the presumption that permanent/time-limited exemptions will be granted for individual areas and that the ban would bring about an increase in the replacement of amalgam fillings.

It is difficult to say how large a reduction in discharges will be obtained with a ban on mercury in products. This is due to comprehensive restrictions on the use of mercury, that have already been and are about to be carried out through voluntary reduction in the use of products containing mercury. This makes it difficult to differentiate between a reduction in the use of mercury that is due to voluntary substitution and a reduction that is due to any possible ban. In addition, products that contain mercury are defined as hazardous waste, and will thus not result in discharges when being discarded or disposed of, if the products are delivered as hazardous waste with respect to the Norwegian Waste Regulations.

One important factor is however that a general ban would prevent us from having mercury in products unless a special exemption has been granted. This would reduce the number of products on the market that contain mercury, as well as reduce discharges from products that by mistake are not delivered in as hazardous waste. Another central point is that a large source of mercury discharges in Norway is long-range pollution. A general ban on mercury in products would be able to serve as an important signal to other countries that it is possible to do something about the use of mercury, and that in the long run can also give reduced discharges in Norway.

There is uncertainty associated with the impacts of both the benefits as well as the costs. Neither is it possible in practical terms to quantify these impacts. This makes it difficult to say anything for certain about the socioeconomic profitability of the ban. Mercury is however a priority substance and the Report to the Storting (White Paper) No. 21 (2004-2005) has as its objective that the use of mercury must be reduced significantly before 2010. A ban on mercury in products would be a contribution to achieving this goal.

### Other Effects

A general ban on mercury in products would probably have a limited impact on Norwegian production, and the ban would thus not have any significant effect on employment. The administrative costs associated with the proposal are estimated to be low, but it would be necessary to have some follow-up and inspection.

## 6. Proposal for Regulations

The proposal involves a general ban on mercury in products, with specific exemptions. The regulations ban both substances and mixtures of substances containing mercury (first subsection) and articles that contain mercury (second subsection).

The present section 2-6 of the Norwegian Product Regulations will be amended, with the important difference that the ban is no longer associated with the areas of use listed, but rather is proposed to be formulated in general.

### **The difference between substances/preparations and articles**

The proposal concerns substances on their own and preparations with mercury being banned from both being sold as well as used, whereas for articles only a ban on their sale is being proposed. SFT regards a ban on the continued use of existing products containing mercury as hardly appropriate, among other reasons because it would generate a lot of waste that appears to be unnecessary in light of the fact that the continued use of the products does not involve any noteworthy danger of injuries to the health or pollution of the environment. In addition, SFT regards compliance with a prohibition on the use of products containing mercury to be extremely difficult to check. For substances and preparations on the other hand, continued use could cause health and pollution-related problems through leakage to the environment.

Since the extent of the prohibition is different, it is necessary to establish what a preparation is and what is an article. What is meant by a preparation is mercury as a constituent part of a preparation or an alloy, for example mercury in antifouling, wood impregnation, amalgams or thiomersal. By an article what is meant is a product that has a mercury component. Examples of such products are switches, thermometers and other measurement instruments. The use of an article that contains a mercury component in pure form or as a preparation is consequently not being proposed to be banned, but rather only banned from being sold. SFT regards it as fundamental that all products containing mercury will either be substances/preparations or articles and will be included by the ban in either the first or the second subsection.

### **Articles for analysis and research purposes**

Thermometers are regulated in the current section 2-6. The Norwegian Product Regulations have, as mentioned previously in the section on measurement devices, a demarcation of their area of use in section 1-2. Under section 1-2, products for analysis and research purposes are thus exempted from the regulations unless something is specially stated otherwise in the individual provisions. This means that thermometers containing mercury for analysis and research purposes will also be permitted unless it is specifically mentioned in section 2-6 that such is forbidden. SFT is of the opinion that the ban on mercury-containing thermometers also for analysis and research purposes must continue to be maintained. Furthermore, SFT is of the opinion that other measurement devices such as manometers, barometers and blood pressure gauges should also be banned for analysis and research purposes. This is included in the second subsection of this section (articles).

### **Demarcations in the proposed regulations**

The impact covers products to which mercury has been added intentionally. SFT is of the opinion that it is not appropriate that mercury that is found today, for example in coal, ore and concentrated ore shall be included by these proposed regulations.

### **Concentration boundaries**

SFT has in the project entitled "Ban on the use of hazardous substances in consumer products" suggested a concentration limit of 0.001 percentage by weight of mercury. The boundary is set on the basis of the technical analysis possibilities, in order to avoid having inappropriate pollution banned and such is also viewed in relation to the regulations in a second body of regulations, including with the Norwegian Food Safety Authority and boundaries that the Swedish construction supply industry operates with. In terms of checks it will be simpler with one established threshold value than a formulation concerning whether mercury has been added or not. Such would thus be included in the proposed regulations for mercury.

### **Other products that are regulated in the Product Regulations**

In the Product Regulations mercury is in addition to being in thermometers also regulated in electrical and electronic equipment, batteries and vehicle components. SFT will thus refer to these provisions in the proposed body of regulations.

### **Deadlines for exemptions from the proposed regulations**

Areas of use that require time-limited exemptions from a general ban must be justified in need for developing or standardising alternatives or giving the requisite time to invest in new equipment, both due to economic and production-related causes. SFT proposes the same date for all time-limited exemptions even though some of the use areas can have the use of mercury phased out earlier.

### **Remarks for section 2-6 in the regulations**

It is proposed that the following be mentioned under the comments for section 2-6 of the regulations:

*The dental treatment must be in accordance with "Guidelines for the use of tooth restoration materials" prepared by the Norwegian Directorate for Health and Social Affairs in 2003 as amended.*

### **Further work**

Notification of the proposal for amending section 2-6 of the Norwegian Product Regulations will be given to the EU and the WTO.

## 7. List of References/Contacts

### Reports/documents:

- Norwegian Ministry of the Environment (2005): Action Plan to Reduce Discharges of Mercury.
- The Norwegian Pollution Control Authority (2005): Hazardous substances in Products – Data for 2003. TA 2087/2005.
- Swedish Chemicals Agency (2004): Mercury - Investigation of a General Ban. KemI Report 2/04.
- The Norwegian Directorate for Health and Social Affairs (2002): Amalgam Use in the Norwegian Dental Service in 2002 (Amalgambruk i norsk tannhelsetjeneste i 2002).
- The Norwegian Directorate for Health and Social Affairs (2003): A National Clinical Guideline for the Use of Dental Filling Materials. Report IS-1136.
- SFT (2005): Consultative statements on the “Action Plan to Reduce Discharges of Mercury”.
- Norwegian Competition Authority (2005): Free Trades - Freer Competition? (Frie yrker - friere konkurranse?). No. 3/2005.
- Adverse Reaction Unit (2004): Annual Report 2004.

### Contacts:

- EE Branch of Trade (Elektro- og elektronikkbransjen)
- Abelia (the Confederation of Norwegian Business and Industry’s association for knowledge-based and technology-based enterprises)
- ICT Norway (IKT-Norge) (the trade organisation for the ICT industry in Norway)
- The Norwegian Electrical Association (Elektroforeningen) (EFO)
- Renas (recycling company for EE waste)
- The Norwegian Directorate for Health and Social Affairs (Sosial- og helsedirektoratet)
- Norwegian National Insurance Administration (Rikstrygdeverket)
- The Norwegian Food Safety Authority (Mattilsynet)
- The Norwegian Medicines Agency (Statens legemiddelverk)
- Norwegian Directorate for Nature Management (Direktoratet for naturforvaltning)
- Norwegian Institute for Water Research (NIVA)
- Norwegian Institute of Public Health (FHI)
- Norwegian Accreditation (NA)