

KEMI

Report

No 4/04

Mercury

– investigation of a general ban

Report by the Swedish Chemicals Inspectorate in
response to a commission from the Swedish Government

Mercury

– investigation of a general ban

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FOREWORD

In November 2003 the Government commissioned the Swedish Chemicals Inspectorate (KemI)¹ to report by 30 June 2004 on whether it is possible to introduce a general national ban on the handling, import and export of mercury, and if so how such a ban could be framed.

The work within KemI has principally been carried out by Petra Ekblom (project leader), Åsa Blomberg, Åsa Edell, Ulla Falk and Anna Olsson. Jerker Forssell has contributed with experience and expertise within the mercury field, Inger Lindqvist has contributed with statistical information and Barbro Sillrén with experience from the field of enforcement. Anette Jakobsson has provided administrative support.

In the part which deals with dental amalgam the work has been carried out in collaboration with the National Board of Health and Welfare, from which Ing-Marie Olsson and Agneta Ekman have participated. There has also been collaboration with Anna Josefsson of the Medical Products Agency (MPA) as regards the Medical Devices Directive [93/42/EEC].

A large number of companies, industrial organisations, trade organisations, research institutes, non-governmental organisations and public authorities have contributed factual data and also made valuable comments on the content of the report. Two study visits have been made to assist with the task and these have been a great help to the investigation. Consultant Anders Östman, Kemiinformation AB, has examined the possibilities for a ban on equipment containing mercury.

KemI would like to thank everyone who has contributed to the investigation and to the production of the report. Their help has been invaluable.

Sundbyberg, June 2004

Petra Ekblom

¹ Swedish and international organisations mentioned in the report are listed in the glossary with their name in full and abbreviated name.

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SUMMARY

Mercury is one of the most hazardous environmental toxins and is a threat to human health and the environment. Mercury cannot be broken down but accumulates in soil, water and living organisms. The more mercury is supplied to society the more the levels in the environment increase. It is therefore of great importance that the use and release of mercury should be eliminated.

Sweden has up to now been successful in the phasing-out of the use of mercury. At the start of the 1990s, mercury-containing instruments and electrical components were prohibited and an export ban was imposed on mercury, its chemical compounds and preparations that contain mercury. Restrictions for mercury have also been introduced within the EU, e.g. for batteries.

However, areas of use remain - and new ones may arise - which are not covered by current legislation. A general ban would correspond better with the Swedish environmental-quality objective "A non-toxic environment" which implies, among other things, that newly produced goods should as far as possible be free from mercury before the end of 2003².

The commission

In November 2003 the Government commissioned the Swedish Chemicals Inspectorate (KemI) to report by 30 June 2004 on whether it is possible to introduce a general national ban on the handling, import and export of mercury, and if so how such a ban could be framed.

In accordance with this commission, an analysis of EC law has been carried out to identify within what areas it is possible to introduce stricter national rules compared with the EU. The investigation's impact assessments have been concentrated on these areas together with areas of application, which up to now have been unregulated within the EU and in Sweden. The principal applications which the investigation covers are dental amalgam, analytical chemicals, disinfection of medical equipment, research and development, the chlor-alkali industry, cosmetics, and equipment with mercury containing instruments and components.

Proposal

KemI proposes that a general ban should be introduced which prohibits mercury³ or goods that contain mercury *being placed on the Swedish market or exported commercially from Sweden*. The proposal also contains a ban on the *use* of mercury. Goods that are already on the market or are in use may continue to be used.

² KemI, and later the Swedish Environmental Objectives Council, have in a deeper evaluation of "A non-toxic environment" proposed that the objective for mercury in remaining applications should be deferred to "as soon as possible but at the latest by 2005".

³ By "mercury" is also meant chemical compounds and preparations containing mercury.

The proposal also contains a ban on the *export of waste* that contains mercury. KemI proposes that the Swedish Environmental Protection Agency should have the possibility of granting exemptions for the export of waste for recovery in individual cases if there are special reasons and also of imposing the condition that the mercury shall be re-imported into Sweden for final disposal.

Mercury which occurs naturally, e.g. in coal, ores and ore concentrates, has been excluded from the ban since this investigation only covers mercury as an intentional additive in chemical products and goods. KemI considers, however, that it is important that a separate investigation be made of the possibilities for and impacts of a regulation of the export of mercury especially in ore concentrates.

KemI has identified a number of areas where harmonised EC legislation makes it very difficult to introduce national rules and these are therefore excluded from the ban in the proposed ordinance. This applies, for example, to batteries, light sources and vehicles.

In addition, KemI has made the judgement that there is a need for time-limited⁴ exemptions from the ban for certain uses, see below. On the assumption that the proposed ordinance comes into force, KemI intends to introduce general exemptions for these uses in its regulations. KemI also proposes that it should have the possibility of granting exemptions from the general ban in individual cases—if there are exceptional reasons.

Dental amalgam

KemI judges that there are strong grounds for banning amalgam⁵ for environmental reasons. From a health point of view there is every reason to apply a precautionary approach. There are other dental filling materials available on the market which meet the needs encountered in normal dental care for children and adults. Within hospital dental care, there may be a need to use amalgam for treating adult patients in exceptional cases where for special medical reasons other treatment methods cannot be used to give a sufficiently good result. KemI and the National Board of Health and Welfare therefore propose such an exemption until 31 December 2008. The proposal contains a special requirement for the dentists carrying out the treatment to keep records so that the need for the exemption can be evaluated.

Analytical chemicals

Mercury compounds are used for various kinds of analysis in many different situations. KemI judges that its use can be phased out in most of the applications, given time for the development and testing of alternative methods. For some areas a special need for exemptions from the general ban has been identified, as follows:

⁴ The dates stated are based on the assumption of a general ban coming into force on 1 July 2005.

⁵ Throughout this document "amalgam" means "dental amalgam" unless otherwise stated.

Analysis of mercury

Mercury is an element that will always need to be monitored as regards its occurrence and residue levels. KemI proposes therefore that mercury compounds for the analysis of mercury be exempted from the general ban with no time limit.

Analysis in the medicinal products sector

In the medicinal products sector there are specific standardised analytical methods for products, raw materials, etc, which are collected in pharmacopoeias. In EC directives there are requirements that the pharmacopoeias be complied with. KemI therefore proposes an exemption until 31 December 2012 to give a reasonable time for the development of new analytical methods and their inclusion in the European Pharmacopoeia.

Analysis of COD

Chemical oxygen demand (COD) is a measure of the theoretical oxygen consumption of a water sample, i.e. the amount of oxygen needed to break down the organic matter in it. For most applications there are mercury-free alternative methods, but a transitional period is necessary from both technical and in certain cases economic points of view. KemI therefore proposes an exemption until 31 December 2008.

Medical diagnosis

At present, there is no alternative to mercury in making certain medical diagnoses. KemI proposes that mercury compounds be exempted for analysis and also research and development in the field of medical diagnostics until 31 December 2008.

Other analysis

Since it is difficult to form a comprehensive picture of each individual application and every alternative KemI proposes that mercury compounds for analytical use—other than those uses specified above—should be exempted from the general ban until 31 December 2008 to make possible the development of and changeover to mercury-free analytical methods.

Research and development

In addition to the fact that mercury compounds are used for analyses within research and development in industry and universities there are other examples of use in R&D, e.g. as catalysts or inhibitors and in environment- and health-oriented research. By including the use of mercury in R&D in the ban, KemI wants to hinder new applications of mercury. To make possible the development of alternative methods KemI considers that an exemption for mercury compounds for R&D is justified until 31 December 2008.

Chlor-alkali production

KemI judges that a national ban on the use of mercury for chlor-alkali production creates no further impacts on the companies concerned beyond those that follow from the EC Integrated Pollution Prevention and Control Directive [IPPC Directive, 96/61/EC]. In accordance with the Government's previously announced target and

Sweden's international commitments it is proposed that the use of mercury for chlor-alkali production shall cease on 31 December 2009.

Seam welding

Seam-welding machines are used in the manufacture of ventilation ducting and cans. The machines that are used for straight seams can be modified to use a mercury-free technique. But there is currently no alternative technique for curved seams. KemI proposes that seam-welding wheels as spare parts and metallic mercury for refilling them be exempted from the general ban until 31 December 2010 for the welding of straight seams and until 31 December 2014 for curved seams to allow time for conversion and the development of alternative techniques.

Other uses

In addition to the above applications, time-limited exemptions are proposed from the general ban for using mercury for *disinfection of certain medical equipment*, in *tracking devices for wildlife* and in *thermometers for flash-point determination*.

Impacts

The aim of a general ban is to reduce as far as possible the use and supply of mercury to society and hence to the environment. The proposal for a general ban is judged to lead to a reduction in the new supply of mercury in chemical products and goods to society from about 340 kg (2003) to about 260 kg per annum. When the majority of the proposed exemptions have expired after three to five years, it is calculated that the supply of mercury will decrease by about a further 70 kg per annum to about 190 kg.

It is principally the bans on amalgam and analytical chemicals that produce the reduction in the new supply of mercury. The use of amalgam has been identified as the single largest source of mercury in sewage sludge, and crematoria are a large source of emissions to air in Sweden. Therefore a ban on amalgam is very important from an environmental point of view. The use of mercury compounds for analytical purposes risks the contamination of sewage sludge and leads to the production of mercury-contaminated waste which must be dealt with. A ban in accordance with the proposal implies that these quantities will decrease and in the long run be minimised.

According to the proposal, the two Swedish chlor-alkali plants will have to cease using mercury at the end of 2009. The about 400 tonnes of mercury used in the process must then be dealt with as hazardous waste and prepared for final disposal. The release of about 40 kg of mercury per annum in process-related discharges will then also cease.

KemI's judgement is that Swedish companies have the possibility to comply with the proposed regulation of mercury. For the companies and users where the investigation has indicated significant adverse impacts, time-limited exemptions from the general mercury ban have been proposed in order to facilitate adaptation and the development of alternative methods. The transition period proposed will also take account of the situation of small enterprises. Companies and users will thus

be given time to adapt themselves to the new rules. The impacts of the proposal on companies and users will therefore be in reasonable proportion to the positive effects the proposal will have on the environment.

1 INTRODUCTION

1.1 The commission

In November 2003 the Government commissioned KemI to report by 30 June 2004 on whether it is possible to introduce a general national ban on the handling, import and export of mercury, and if so how such a ban could be framed. The commission includes metallic mercury and its chemical compounds and preparations and goods containing mercury.

According to the commission KemI shall, to the extent that it is justified, propose exemptions from the general ban. Proposals for statutory changes are to be submitted and impact assessments, which include effects for individual persons and the economy from environmental and economic points of view, shall be reported. The proposed statutory changes are also to be subjected to impact assessment in accordance with the requirements in Swedish Government Ordinance (1998:1820) on the special impact assessment of the effect of regulations on small enterprises (SimpLex Ordinance).

The task is to be carried out in collaboration with the National Board of Health and Welfare where it concerns dental material (amalgam). Beyond this there should be consultation with other public authorities affected. Account must be taken of EC legal principles and other international principles and commitments.

1.1.1 *Government's reasons*

Sweden has up to now been successful in the phasing-out of the use of mercury. The Government notes, however, that areas of use remain—and new ones may arise—which are not covered by current legislation. A general ban, possibly with certain specified exemptions, would also correspond better with the national environmental quality objective "A non-toxic environment" which implies, among other things, that newly produced goods shall as far as possible be free from mercury before the end of 2003⁶.

1.2 Interpretations and scope

1.2.1 *New supply*

Large quantities of mercury are stored in goods that are currently used in society. In many cases, the use phase of the goods causes no great environmental problem; the important thing is that the mercury is dealt with in an environmentally sound way when the goods come to be scrapped. KemI has chosen to direct the investigation towards the new supply of mercury to society in order to achieve the phasing-out of the substance in the long run. Possibilities for or obstacles to a general ban on the

⁶ KemI, and later the Swedish Environmental Objectives Council, have in a deeper evaluation of "A non-toxic environment" proposed that the objective for mercury in remaining applications should be deferred to "as soon as possible but at the latest by 2005".

use of existing mercury-containing goods have therefore not been examined. Nor have any impact assessments for a ban on the use of existing mercury-containing goods been carried out. On the other hand, the use of mercury, mercury compounds and preparations containing mercury has been included since the use phase often implies a risk of the dispersion of mercury into the environment and the generation of mercury-containing waste.

KemI has interpreted the commission as concerning mercury as an intentional additive in chemical products and goods. During the investigation it has emerged that the fact that it occurs naturally, e.g. in ores, implies that large quantities of mercury are exported from Sweden. For reasons of time, these goods have not been included in the investigation but KemI considers that it is important that a separate investigation be made into this issue (see discussion in Para 7.1.2).

1.2.2 Handling

The term handling is defined in Chapter 14 Section 4 of the Swedish Environmental Code (Miljöbalken) and comprises manufacturing, processing, treatment, packaging, storage, transport, use, safe custody, destruction, conversion, marketing, transfer of ownership and similar procedures.

Widely different areas of law are covered by the Swedish Environmental Code's definition of handling. Since KemI's principal area of responsibility does not cover all these activities, e.g. waste handling, the decision was taken to interpret the commission from the point of view of KemI's own area of responsibility. This implies that there has been no examination of possibilities for or obstacles to a general national ban on the transport of mercury or on the handling of mercury-containing waste within Sweden (the export of waste is included). No impact assessments for these types of handling have been carried out either. It is of course also apparent that some types of handling must be able to go on long after any general ban on the use of mercury in products and processes has been introduced.

1.3 Procedure

1.3.1 Methodology

A legal analysis has been carried out to examine possibilities for and obstacles to a national ban as regards EC law. The legal analysis has then been the basis of investigations of the need for possible exemptions from technical and economic aspects plus analyses of economic and environmental impacts on the economy, individual persons and society. Based on the legal analysis plus impact assessments a draft ordinance has been produced. In accordance with the SimpLex Ordinance [1998:1820], this draft proposal has been subjected to a separate analysis of the effects of the regulations on small enterprises.

Anders Östman of Kemiinformation AB who was engaged as a consultant produced the information for the investigation of the need for exemptions permitting the placing of mercury-containing equipment on the Swedish market.

1.3.2 Consultation and collaboration with other public authorities affected

During the work there has been consultation with a number of national authorities such as the Medical Products Agency (MPA), the Swedish Environmental Protection Agency (SEPA), the National Food Administration (NFA), the Swedish Work Environment Authority (SWEA) and the National Board of Trade. Local environmental administrations have also been consulted in certain cases.

The part of the work relating to dental amalgam has been carried out in collaboration with the National Board of Health and Welfare, which has responsibility for its use in health care. Collaboration has also taken place with the Swedish Medical Products Agency concerning the Medical Devices Directive.

1.3.3 Consultation with interested parties

To collect data for the impact assessments a questionnaire was sent out (Annex 5) to a large number of companies, industrial organisations, trade organisations, research institutes, non-governmental organisations and public authorities. The questionnaire was also translated into English and both language versions were made available on KemI's web site. The data collection was carried out in consultation with the Board of Swedish Industry and Commerce for Better Regulation (NNR). In addition to individual contacts with a large number of interested parties, meetings were arranged to discuss specific problem areas with the parties affected. As part of the commission two study visits were made concerning dental amalgam. Those interested parties which wished to were given the opportunity to comment on a draft of the report which was also made available on KemI's web site. In annexes to the Swedish version of this report, the names of organisations, companies and authorities involved in the investigation are listed.

1.3.4 References

As far as possible, references are given to the documents used in the investigation. Where no source is indicated this is because either the account is based on a number of sources, which have been combined together, or there were judged to be special reasons to allow the source to remain anonymous.

2 BACKGROUND

2.1 Current regulations for the handling, import and export of mercury

Mercury is regulated in a number of EC directives. The directives relevant to this investigation are described in Annex 4, where the legal possibilities for and obstacles to a national ban are analysed. Also indicated there is where the directives are incorporated into Swedish legislation.

Regulations for mercury in goods that are not covered by EC legislation are mainly contained in Sections 8-11 of Ordinance (1998:944) Concerning Prohibitions etc in Certain Cases in Connection with the Handling, Import and Export of Chemical Products (Annex 1). The title of the Ordinance is a result of a later consolidation with other ordinances and is therefore misleading. The original ordinance was passed in 1991 and most of the bans came into force in 1992-93.

The Ordinance states by way of introduction that *mercury and chemical compounds and preparations* containing mercury may not be exported professionally from Sweden. Its purpose is primarily to prevent the export of mercury-containing waste, but in practice exports of chemical products that contain mercury, e.g. amalgam and analytical chemicals, are also banned.

According to Section 9, certain *goods* that contain (metallic) mercury may not be manufactured or sold commercially. The ban covers thermometers and other measuring instruments plus electrical components such as relays and circuit-breakers. These goods may not be imported from third countries or exported from the country. Since 1996, this paragraph has granted a power to KemI to issue rules that the bans shall also apply in relation to *equipment* containing a regulated good. This power has not been utilised.

According to Section 10, goods may further not be used if they were not in use before 1 January 1995. The provision is an accommodation to Sweden's accession to the EU and the difficulty of preventing imports from other EU countries. It also counters the possibility of getting round the bans in Section 9 by selling empty goods, which are then filled with mercury by the user.

According to the Ordinance, KemI may if there are special reasons issue regulations concerning exemptions. Such exemptions are listed in Annex 3 of KemI's Regulations, [KIFS 1998:8] (see Annex 2). The possibility of granting exemptions was utilised more frequently when the ordinance was new. Nine exemptions remain today, relating only to the supplying of spare parts.

If there are exceptional reasons KemI may, according to the Ordinance, grant exemptions in individual cases. During the first half of the 1990s a total of 43 applications for exemptions were made (about ten per annum) of which 75% were granted. During the second half of the 1990s, the number of applications almost doubled to a total of 78 (about twenty per annum). The most probable cause is that

many of the earlier exemptions from the ban had expired. About 60% of these applications were granted. During the last three years, 32 applications for exemptions have been submitted (about eight per annum) and 62% have been granted.

Current bans may treat Swedish companies unfairly, partly because they are not allowed to install the banned goods in equipment although such equipment can be imported from another country with no obstacle, and partly because they may not export chemical compounds or regulated goods. Behind this lies the principle that goods regarded as too dangerous to be permitted in Sweden should not be exported either. The power to grant exemptions has provided the possibility of taking adverse effects of this principle into account in individual cases.

To sum up, where commercial manufacture and sale within the country are concerned the ban currently in force is limited to a small number of goods. The export of chemical products and other goods, on the other hand, is already greatly restricted today.

2.2 Previous notification to the EU concerning extended regulation

At the beginning of 1999, the Ministry of the Environment initiated work on a proposal to extend regulation of the use of mercury to cover the chlor-alkali industry, light sources, analytical chemicals and reagents, and seam-welding wheels. In parallel with this KemI started an investigation of the need for possible exemptions for the three last-named applications. Consultants produced studies on each of them, which were used as the basis of discussions about the formulation of regulations at meetings with industry organisations and companies affected. Preliminary proposals for regulations with certain time-limited exemptions were circulated for comment within the industries affected and then the composite proposal was circulated. From the response to this consultation, KemI judged that it was possible to implement a ban with time-limited exemptions without causing serious impacts on the companies affected.

The National Board of Trade notified the proposals for an amended ordinance and regulations to the EU and WTO in July/August 2000. The European Commission, France and the United Kingdom queried the introduction of provisions concerning light sources, since the Commission had earlier in that year published a proposal for regulating certain hazardous substances, including mercury, in electrical and electronic products. In January 2001, Sweden therefore notified the Commission that the proposals had been withdrawn. The Ministry of the Environment's ambition was to submit a revised proposal from which the regulation of light sources had been deleted, but this has not yet been done.

Now that the question of introducing a ban on, among other things, analytical chemicals and reagents, and seam-welding wheels has been raised again, the data from 1999 have been judged to be too old to reflect the current situation sufficiently

reliably. The impact assessments for these two areas have therefore been based for the most part on information collected as part of the present commission.

3 MERCURY IN SOCIETY AND THE ENVIRONMENT

3.1 Environmental and health situation in Sweden

Despite Swedish efforts to limit the use and release of mercury, mercury deposition over Sweden is still large. The Swedish Environmental Protection Agency (SEPA) has estimated deposition at about 4.2 tonnes per annum, of which most comes via long-distance atmospheric transfer, principally from Europe but also from other parts of the world. Swedish emissions to the air are calculated to be 0.7 tonnes. Globally, the greatest anthropogenic source of mercury emissions is the combustion of coal [UNEP, 2002]. Other sources of emissions to the air include smelting plants, crematoria (because of amalgam fillings) and waste incinerators. Mercury also gets into soil and water, for example by emissions from industry, leaching from landfills and the spreading of sewage sludge.

Mercury and its compounds, principally methyl mercury, above all have adverse effects on the nervous system and its development, plus adverse effects on the cardiovascular system, immune system, reproductive system and kidneys. Disturbances of the development of the nervous system and toxicity as regards the central nervous system are the most sensitive and best-documented effects. Mercury is converted to methyl mercury by natural processes and bio-accumulates in the food chain. Methyl mercury is transferred to the foetus, passes through the blood-brain barrier and probably retards mental development even at low concentrations. People who eat a lot of fish, shellfish and marine mammals are particularly exposed. [UNEP, 2002]

The limit of 0.5 mg of mercury per kg of fish, which has been recommended internationally by the WHO/FAO, is exceeded in one-kilogram pike in about 50,000 Swedish lakes (about half of the Swedish lakes) [Naturvårdsverket, 2002]. The National Food Administration (NFA) recommends that women who plan to have a baby soon, plus pregnant women and mothers who are breast-feeding, should not eat perch, pike, pike-perch, turbot, eel and large halibut since these often contain high levels of mercury. The recommendation has recently been extended to cover certain species of sea-fish such as fresh tuna. According to the NFA, the rest of the population should eat these fish species a maximum of once a week [NFA web site]. SEPA estimates that an 80% reduction in the mercury content of deposition is needed in order to achieve maximum levels of 0.5 mg of mercury per kg in freshwater fish in the long term [Naturvårdsverket, 2002]. There are also indications that the levels in fish affect reproduction of fish-eating mammals and birds. Mercury levels in fish in the North Sea are also elevated. In the Arctic regions, there are health problems among the population because mercury levels in fish, whales and seals are very high. Levels in polar bears are also very high.

The mercury level in the soil in Swedish forests has increased three to five times compared with the background level. Although mercury deposition has decreased during the last few decades this has not been sufficient to prevent the metal accumulating. Its level increases by about 0.5% per annum in the topmost layer of

forest soils and in southern Sweden is already above the levels which have been shown to affect biological processes and organisms in the soil. This mercury is also a source of methyl mercury via leaching into the water system. [Naturvårdsverket, 2002]

3.2 Mercury in chemical products and goods

Mercury in chemical products and goods can be emitted to the air during the use phase or after scrapping, either via waste incineration or from landfills. The contribution to the total anthropogenic atmospheric deposition of mercury is not negligible. The Swedish Environmental Research Institute Ltd. (IVL) estimated in 1997 that mercury in batteries, measuring instruments, electrical equipment and light sources in Europe contributes 10-14% of mercury deposition in Scandinavia. The largest contribution came from light sources and electrical equipment [Kemikalieinspektionen, 1997b]. The use of amalgam was not included in the Institute's investigation. Estimates from 2002 show that amalgam is the single largest application of mercury within the EU with about 70 tonnes per annum [Concorde East/West Sprl, 2004]. Because of emissions from crematoria, Sweden receives mercury derived from the use of amalgam in Europe.

In addition to emissions to air, some uses can lead to mercury entering sewage sludge. If the level of mercury exceeds 2.5 mg/kg of dry matter, the sludge must not be used as a fertiliser on arable land [SNFS 1994:2]. SEPA has proposed reducing the limit to 1.8 mg/kg of dry matter from 2005 (Lundeberg, personal communication).

To eliminate trade in mercury and reduce the quantities of hazardous waste containing mercury it is necessary to have a ban on chemical products and goods that contain it. To restrict the supply of mercury to society, and thereby take care of the problem at the source, is an effective way to reduce the risks to human health and the environment instead of using pollution control measures and collecting and taking hazardous waste into safekeeping.

There are large quantities of mercury-containing waste within society, and the quantities will increase as goods in use today reach the end of their useful life. It has long been an objective to remove mercury from the ecocycle and on 30 October 2003 the Swedish parliament passed a law that by 2015 waste which contains mercury at least 1 % by weight must be stored permanently deep down in rock. The same will apply to waste that contains at least 0.1 % mercury by weight, if that is reasonable within the meaning of the Swedish Environmental Code [Government Bill 2002/03:117]. The Ministry of the Environment is currently working on a draft ordinance.

3.3 Areas of use and quantities

Mercury is used in a large number of different areas, e.g. in batteries, electrical components, measuring instruments, light sources (low-energy lamps and fluorescent tubes), neon tubes, dental amalgam, medicinal products and cosmetics. It

is also used in laboratories as an analytical chemical and reagent and in the chlor-alkali industry in the production of chlorine and caustic soda. New uses and products, which have not been recognised by the public authorities, turn up now and then. One example is a product used in the theatre to make eyes red, which uses a mercury compound as a preservative. During the investigation information was found about uses that for reasons of time there was no opportunity to investigate as part of the commission. An example is the use of mercury as a catalyst in polyurethane production.

The new supply of mercury to society via chemical products and goods decreased greatly in Sweden during the 1990s. In December 1998 KemI and SEPA published, at the Government's request, an evaluation of the phase-out of the use of mercury [Kemikalieinspektionen, 1998]. Total sales of mercury via chemical products and goods decreased from about 9 tonnes in 1991/92 to about 2 tonnes in 1997. The quantity of mercury sold for chemical products and goods is now about 340 kg (2003). Annex 3 gives quantitative information for each area of use for the three years.

The greatest areas of use today are light sources (121 kg), amalgam (103 kg) and analytical chemicals (53 kg). Use in batteries has decreased very greatly since restrictions were introduced within the EU and is now less than 24 kg. All the data refer to 2003.

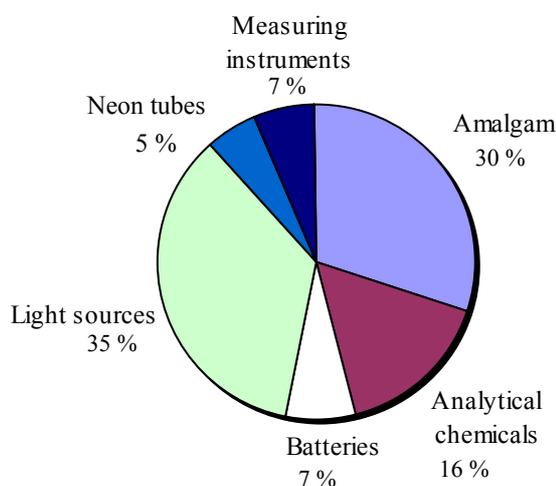


Figure 1. Mercury supplied in chemical products and goods, 2003.

In the two chlor-alkali plants in Sweden there are about 400 tonnes of mercury in use. In 2002 the companies reported discharges to air of about 38 kg of mercury, to water of about 2 kg and residual quantities in the products of about 4 kg of mercury. During recent years the mercury supplied to the plants has come from recovered

mercury, mainly from the waste-treatment company SAKAB, and from the companies' own stocks (Jorlöv and Andersson, personal communication).

Large quantities of mercury are stored in society in the form of amalgam fillings. An estimated 74% of the adult Swedish population has amalgam fillings [SOU2003:53]. In 1993 SEPA estimated the quantity of mercury in the population's teeth as 40-60 tonnes [Naturvårdsverket, 1993]. For Stockholm the quantity in 1995 was estimated as 4.9 tonnes [Sörme et al, 2001, Bergbäck et al, 2001] and in 2001 as about 3.4 tonnes, which would correspond to about 40 tonnes for the whole country [Miljöförvaltningen i Stockholm, 2004].

It is hard to estimate the quantities of mercury in society that are stored in existing goods or as stocks of metallic mercury. Estimates have nevertheless been made. Kemiinformation AB estimated for 2003 the quantities of mercury stored in instruments and equipment as about 15-20 tonnes (Östman, 2004). SEPA estimated in 1999 that there are about 33 tonnes of mercury stored in technical products or as stocks of metallic mercury. The metallic mercury was judged to be a large part of the total quantity (about 10 tonnes). A further quantity of just under 2 tonnes was estimated to be in clinical thermometers in the armed forces and about 2 tonnes in old clinical thermometers, barometers, doorbells, etc, in households. SEPA also estimated that there are probably several tons of mercury within agriculture in the form of stocks of old plant-protection chemicals [Naturvårdsverket, 1999].

3.4 Classification of mercury and mercury compounds

A number of mercury compounds are classified in Annex 5 to the Swedish Chemicals Inspectorate's regulation 1994:12 concerning the classification and labelling of chemical products. These are summarised in Table 1. All are classified as dangerous for the environment (N) and as very toxic (T+) or toxic (T). There is one exception from the latter and that is dimercury dichloride (calomel), which is classified as harmful to health (Xn). Certain compounds are also classified as corrosive (C), irritating (Xi) or explosive (E).

Table 1. Classification of mercury and mercury compounds

Name	CAS number	Classification codes
Mercury	7439-97-6	T; R23 R33 N; R50-53
Mercury compounds, inorganic excluding mercury(II)sulphide and compounds included in Annex 5	-	T+; R26/27/28 R33 N; R50-53
Mercury compounds, organic, excluding compounds included in Annex 5	-	T+; R26/27/28 R33 N; R50-53
Dimercury dichloride (calomel)	10112-91-1	Xn; R22 Xi R36/37/38 N; R50-53
Mercury dichloride	7487-94-7	T+; R28 T; R48/24/25 C; R34 N; R50-53
Mercury oxycyanide	1335-31-5	E; R3 T; R23/24/25 R33 N; R50-53
Dimethylmercury	593-74-8	T+; R26/27/28 R33 N; R50-53
Diethylmercury	627-44-1	T+; R26/27/28 R33 N; R50-53
Phenylmercuric acetate	62-38-4	T; R25-48/24/25 C; R34 N; R50-53
Phenylmercuric nitrate (1), phenylmercuric hydroxide (2) and mixture (3) of 1 and 2	(1) 55-68-5 (2) 100-57-2 (3) 8003-05-2	T; R25-48/24/25 C; R34 N; R50-53
Mercury fulminate	628-86-4	E; R3 T; R23/24/25 R33 N; R50-53
2-Methoxymercuric chloride	123-88-6	T; R25-48/25 C; R34 N; R50-53

4 POSSIBILITY OF A GENERAL NATIONAL BAN ON HANDLING MERCURY FROM THE PERSPECTIVE OF EC LAW

4.1 Introduction

For all legislative acts passed within the EU there must be a legal basis in the Treaties. In each act there is a reference to the article or articles in the Treaties that constitute the legal basis for that particular act⁷. When the legislative provision relates to restricting possibilities for putting something on the market, the choice is essentially between Article 95 and Article 175 of the EC Treaty. The choice is made depending on the main purpose of the act. Article 95 aims at harmonization of the laws of the Member States and at free movement of goods. Article 175 establishes minimum requirements for the environment.

The choice of the legal basis is important for the Member State's possibility of establishing stricter national requirements⁸. The possibility for a Member State to introduce stricter national rules depends on either the legal basis chosen or the content of the secondary law. The content of the secondary law can give rise to different interpretations⁹.

Even if a directive has Article 95 as its legal basis and according to the content of the directive its purpose is the harmonization of the Member States' laws, it is important for the assessment of the possibility of introducing national rules to investigate what aspects have been taken into account in the formulation of the directive. In many cases account has only been taken of health and safety aspects and not effects on the natural environment. KemI judges that there is then a possibility for the Member States to introduce national regulation relating to protection of the natural environment irrespective of the fact that the directive's aim is harmonization. The National Board of Trade does not exclude the possibility of "opening up" a previously harmonized area and argues in accordance with Articles 28 and 30 of the EC Treaty in favour of introducing a Swedish ban on mercury [Kommerskollegium, 2004].

It is important to point out that the legal assessment, which takes place according to the principles that have now been described, creates only an external framework for the possibilities of introducing a national ban on mercury. So that the EC law analysis is comprehensive it is also necessary to take account of, among other things, the proportionality principle.

⁷ EU:s miljö rätt, p. 98

⁸ EU:s miljö rätt, p. 115

⁹ EU:s miljö rätt, p. 124-125

4.2 General EC-law requirements for national regulation

4.2.1 Legal bases

Article 175 of the EC Treaty

The acts which establish minimum requirements for the natural environment, waste and the working environment generally have their legal basis in Article 175 of the EC Treaty and are thus used to deal with environmental protection¹⁰. The underlying aim is protection of the environment. This justifies and permits differences in national regulatory provisions to achieve that aim¹¹. If the legal basis for an act is Article 175 the Member States therefore have the possibility of introducing stricter national limits. This is stated explicitly in Article 176 of the EC Treaty.

Article 95 of the EC Treaty

Article 95 of the EC Treaty refers back to Article 14 of the Treaty whose aim is the creation of the internal market, which covers, among other things, the free movement of goods. The express intention of Article 95 is to make legislation uniform within the whole Community and it therefore aims at harmonisation of national legislation¹². The aim is to make regulation uniform for the benefit of unrestricted free movement of goods within the Community¹³. The Commission shall in its proposals, which are based on Article 95, take as a base a high level of protection as regards health, safety and protection of the environment and consumers.

According to Article 95.10 of the EC Treaty the harmonisation measures taken within the scope of Article 95 shall, if necessary, contain a safeguard clause permitting the Member States to take provisional measures, which shall be subject to a Community control procedure.

4.2.2 Environmental guarantee

If the legal basis for a directive is Article 95 of the EC Treaty the purpose of the regulation is harmonisation and the possibilities for national rules are very limited. The sole possibility for stricter national rules is the "environmental guarantee" in Articles 95.4-8 of the EC Treaty. The environmental guarantee implies, among other things, that a Member State which considers it necessary to apply stricter national rules in an area where harmonisation measures have been decided on has a certain possibility of introducing national provisions based on new scientific evidence related to environmental protection or working-environment protection in order to solve a problem which is specific to that Member State and which has arisen after the decision on harmonisation measures. The Member State must then notify the Commission about the planned provisions and the reasons for introducing them. The Commission then has six months to approve or to reject the national provisions. However, this period can be extended.

¹⁰ EU:s miljö rätt, p. 98

¹¹ EU:s miljö rätt, p. 111

¹² EU:s miljö rätt, p. 111

¹³ EU:s miljö rätt, p. 116

4.2.3 Free movement of goods

If there is no regulation at EU level or if the regulation that exists is not aimed at harmonization the possibility exists for the Member States to introduce national rules. This possibility is, however, not unrestricted since account must be taken of the provision in Article 28 of the EC Treaty that deals with the free movement of goods. Article 30 of the Treaty lays down exceptions from Article 28 and national prohibitions and restrictions are thus permitted if they are based on, among other things, environmental considerations¹⁴.

4.2.4 Proportionality principle

When national rules are introduced (even if the environmental guarantee is used) account must also be taken of the proportionality principle. The proportionality principle implies that no official intervention may go further than is actually necessary to achieve the underlying purpose. The regulation must not be more onerous or far-reaching than can be regarded as necessary to achieve the purpose. There must be a balance between means and ends and it must be probable that the purpose can be achieved with the means used. The restriction must be in reasonable proportion to the purpose¹⁵.

4.2.5 Notification procedure in accordance with 98/34/EC

According to Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations¹⁶, Member States which intend to introduce a national rule must among other things immediately submit to the Commission all drafts of technical regulations (e.g. laws and other enactments which prohibit the production, import, marketing or use of a product¹⁷). The Member State must also report the reason why it is necessary to draw up such a technical regulation. If the intention of the draft is, for example, to restrict the use of a chemical substance for environmental protection reasons the Member State must submit either a summary of or references to all the relevant data about the substance and about known and available substitutes, and indicate what effects the measures are expected to have on public health and on protection of the consumer and the environment. A risk analysis must also be submitted¹⁸.

The notification procedure must provide a basis for other Member States and the Commission to judge whether the national measures contemplated are compatible

¹⁴ See further the European Court's judgement in Case 120/78 Cassis de Dijon.

¹⁵ Sweden and European Law, pp 41-42

¹⁶ Incorporated into Swedish legislation by Ordinance (1994:2029) Concerning Technical Rules, and Ordinance (1998:1470) Concerning Amendments to Ordinance 1994:2029 Concerning Technical Rules.

¹⁷ Article 1. Directive 98/34/EC of the European Parliament and of the Council laying down a procedure for the provision on information in the field of technical standards and regulations.

¹⁸ See further Article 8 of Directive 98/34/EC about an information procedure concerning technical standards and regulations.

with EC law. Without a notification in accordance with the procedure the Member State must not apply the measures to individuals.

4.3 Restricting provisions in the EC's secondary legislation

Mercury is found in a very large number of different areas of application and provisions relating to mercury are therefore to be found in a number of different directives and EC regulations. The account below of the secondary legislation that applies to mercury does not claim to be exhaustive but should cover the majority of the directives and EC regulations that are relevant to a national regulation of mercury. The selection has taken place via studies of the directives that regulate known uses of mercury and via searches in Celex and elsewhere. A survey of both directives and regulations is contained in Annex 4. In addition there is an outline analysis of the possibilities for a ban on the export of mercury-containing waste.

4.3.1 Directives and EC regulations which restrict possibilities for national regulation of mercury

The directives that aim at harmonization of national regulations and take account of protection of the natural environment provide a very limited possibility of introducing national rules concerning bans on the handling of mercury. The possibility is provided only by the environmental guarantee provisions in Article 95.5 of the EC Treaty. The EC legislation for which this is true and which is also relevant to the regulation of mercury is principally the RoHS Directive [2002/95/EC], the Battery Directive [91/157/EEC], the Packaging Directive [94/62/EC], the Vehicle Type-Approval Directive [70/156/EEC], the Directive on end-of-life vehicles [2000/53/EC], the In Vitro Diagnostic Medical Devices Directive [98/79/EC] and the Veterinary Medicinal Products Directive [2001/82/EC] plus the Regulation on the authorization of human medicinal products and veterinary medicinal products [EEC No 2309/93], but only as regards veterinary medicinal products. As regards human medicinal products [2001/83/EC] further assessment about possibilities for introducing a national ban on mercury might be motivated, see further the discussion in Annex 4.

Theoretically, all the new-approach directives¹⁹ and other directives involving some form of authorization which shall apply throughout the whole Community²⁰ and aiming at the harmonization of Member States' laws and taking account of protection of the natural environment prevent Member States from introducing national bans on these products.

4.3.2 Directives and EC regulations which do not restrict national regulation of mercury

There are also directives, which although aiming at harmonization of Member States' national rules, take account only of health and safety and not protection of

¹⁹ This applies at least in theory even if all the new-approach directives are in practice not relevant to the regulation of mercury.

²⁰ What is said in fn. 13 applies also to this type of directive.

the natural environment. This implies a possibility for the Member States to introduce national rules taking account of the natural environment. The directives which are relevant in this respect and which are important for national regulation of mercury are principally the Medical Devices Directive [93/42/EEC], the Toy Safety Directive [88/378/EEC] and the Cosmetics Directive [76/768/EEC]. Toys, however, are also regulated in the RoHS Directive and there is thus a certain limitation on introducing national rules concerning toys.

The Limitations Directive [76/769/EEC] aims at harmonising Member States' laws concerning the areas of use that are regulated in the Limitations Directive. The rules concerning mercury contained in the Limitations Directive mean a total ban on the use of mercury in the regulated areas of use. Other areas of mercury use that are not mentioned in the Limitations Directive are not covered by the area harmonised by the Directive, thus enabling the Member States to introduce national rules. Nor does this Directive thus involve any limitation of the possibilities of introducing national rules concerning bans on the handling of mercury.

The Plant Protection Products Directive [79/117/EEC] involves a total ban on the use of mercury, which means that it is possible for the Member States to introduce national rules concerning bans on mercury.

Nor do the Biocidal Products Directive [98/8/EC] and the Regulation on the export and import of dangerous chemicals [EC No 304/2003] involve any restriction of the possibilities of introducing a national ban on mercury.

4.3.3 EC Regulation on the transport of waste

Disposal and recovery of waste are regulated, *inter alia*, in Council Regulation 259/63 on the monitoring and control of waste transport within, to and from the European Community. The Regulation distinguishes between waste exported for disposal and waste exported for recovery. According to Article 4.3.a) i) the Member States, in order to apply the principles of proximity, prioritization of recovery and self-sufficiency at Community level and national level in accordance with Directive 75/442/EEC, may take measures to ban, wholly or partially, or systematically object to, the transport of waste. The Article applies, however, only to the export of waste for disposal and there is no corresponding regulation of the export of waste for recovery. It is thus possible to impose a national ban on the export of waste for disposal, at least. Against the background of the European Court's judgement²¹ it ought to be possible to prevent mercury from being exported from Sweden even for recovery if this is done for environmental-protection reasons. It should therefore be possible to make national provisions for preventing the export of mercury-containing waste for disposal and to introduce conditions that mercury arising from waste that is exported for recovery must be sent back to Sweden for final disposal.

²¹ Court's judgement dated 25 June 1998. *Chemische Afvalstoffen Dusseldorp BV and others versus the Minister van Volkshuisvest Ruimtelijke Ordening en Milieubeheer*. Request for Advanced Decision: Council of State, Netherlands. Transport of waste intended for recovery - Principles of self-sufficiency and proximity. Case C-203/96.

5 STANDARD METHODS

National bans on the use of hazardous substances can come into conflict with the need of companies and institutions to carry out measurements or analyses by standard methods, i.e. methods on which agreement has been reached within European (CEN) or international standardisation organisations (ISO). Because national legislation overrides standards the CEN and ISO standards that contain a requirement for measurement with mercury-containing instruments have not been implemental as Swedish standards, since the current regulation of certain mercury-containing goods was introduced. SIS, the Swedish Standards Institute, has in such cases requested exemptions for the standards in Sweden. Corresponding problems will occur if a general ban should be introduced for analytical chemicals and reagents.

In the examination of exemptions and dispensations for regulated goods KemI has since the beginning of the 1990s primarily investigated, from case to case, whether there is a technically possible alternative to the desired function. Other special or exceptional reasons for exemption/dispensation, such as dependence on being able to carry out a measurement by standard methods, have been regarded as of secondary importance in such examinations. KemI has found reason to deviate from the stated principle only in a few cases where, to satisfy other legislation, the use of a particular standard method is prescribed, which, in its turn, prescribes or for technical reasons requires the use of a mercury-containing instrument.

Within the framework for the current ban on mercury in measuring instruments it has been claimed in a number of cases that it is necessary to carry out measurements with mercury thermometers in order to conform with various standard methods, especially methods from the USA (ASTM). Closer examination has shown that these methods do not always prescribe mercury thermometers but, rather, a particular accuracy and in particular traceability in the analysis. In ASTM methods, for example, the instrument is often specified in such a way that it will contain a thermometer pocket or holder that is designed for a specific mercury thermometer. In isolated cases, such as flash-point determination, the ASTM methods prescribe a certain size of bulb that arises from the shape of the mercury ball. In these situations, therefore, there are no actual technical obstacles to changing over to alternative techniques where they are available (Östman, 2004).

The analysis of EC law has shown that it is possible to extend the current national ban to areas within which a large number of standard methods occur, for example in chemical analyses. KemI considers that the principles that have been developed and the experience that has been obtained in the case of handling dispensations within the current ban should be a guide in the case of a general ban as well. The starting point should thus be to investigate case by case whether there is mandatory legislation and whether there are alternative methods that are technically comparable. These principles have therefore governed the structure of the impact assessments that have been carried out as part of the present commission.

Sweden is, together with a number of other countries in Europe, actively seeking the removal of mercury and mercury compounds from standards and some progress has been made. A national ban on mercury means that Swedish representatives can put forward proposals for amending standards in different standardisation committees

more forcefully. According to the Swedish Standards Institute's (SIS) reply to our questionnaire Swedish representatives have often highlighted problems with the use of, in particular, elementary mercury in measuring equipment, but up to now they have not found much sympathy for these views in standardisation committees and in votes within the ISO and CEN.

All standards are reviewed every five years and there is then the possibility of making changes, for example exchanging undesirable substances or equipment for other alternatives. It is, however, possible to change a standard ahead of time by a supplement (amendment).

6 IMPACT ASSESSMENTS OF CERTAIN USES

An analysis of the prerequisites under EC law for a national ban is set out in Chapter 4. The legal analysis has identified within which areas of use it is possible to introduce stricter national rules and this analysis provides the framework for the investigation carried out. The impact assessments described in this chapter focus on the areas of use identified in the legal analysis and the areas of use which have not so far been regulated in Sweden or the EU:

- amalgam
- analytical chemicals and reagents
- disinfection of medical equipment
- research and development
- the chlor-alkali industry
- cosmetics
- equipment

The analyses throw light on the existence of alternatives to mercury in the above-mentioned uses and on whether these are available on the market or whether time is needed for their development. In certain cases it has been difficult or impossible to obtain a comprehensive picture of uses and alternatives where the use is widespread throughout the Swedish economy. A complete and detailed study has not been possible in these cases during the short time available for this commission.

The impact assessment explores positive and negative effects for individual persons and the economy from environmental and economic points of view. To the extent that it has been possible and of interest, possible impacts on society have been analysed in broad outline. The impacts have been analysed from the point of view of various parameters. Some of these parameters are: the economy and competitiveness; environmental effects; health effects; safety aspects (technical/hygiene requirements); and research and education.

A special impact assessment has been carried out on the completed draft ordinance in accordance with the SimpLex Ordinance [1998:1820] on the effect of regulation on small enterprises. The SimpLex analysis is found in Chapter 8.

For each area of use there are conclusions and proposals for regulation, with possible exemptions. The exemptions are, in general, time-limited and the number of years indicated is based on the assumption that a general ban will come into force on 1 July 2005.

6.1 Amalgam

6.1.1 A short historical retrospect

Amalgam has been used as a tooth-filling material since the 1800s. A debate on the risks of leakage of mercury from the fillings began as early as the middle of the last century. In 1938 the Swedish parliament decided on free dental care for children and the expansion of public dental care by the county councils started. The predominant tooth-filling material was amalgam. [SOU 2003:53]

Both health and environmental risks connected with the use of amalgam have been debated since the 1970s. During the 1980s a number of expert groups and investigations were set up and in 1991 the National Board of Health and Welfare investigated at the government's request the preconditions for phasing out amalgam as a tooth-filling material. The investigation proposed a phasing-out process in which amalgam would cease to be used in dentistry for children and young people from 1 July 1995 and cease to be used entirely by 1997. Parliament and government decided in 1994 that the use of amalgam should be phased out by 1997. As a stage in this, an agreement was made between the state and the county councils in 1995 that amalgam should be phased out from children's dentistry (Government decision 1995). [SOU 2003:53]

KemI was requested by the Government to evaluate by 1 July 1996, in consultation with the National Board of Health and Welfare, the phasing out of amalgam. In the investigation it was established, *inter alia*, that total phasing out by 1997 was not possible but that its use could be reduced further. The investigation showed that despite the 1995 agreement amalgam was still used for fillings when there were other alternatives and, remarkably, often for the repair of children's teeth. [Kemikalieinspektionen, 1996]

To make amalgam more cost-neutral against other filling materials, Parliament decided in 1999 that no financial support should be given for amalgam fillings via the national dental insurance.

6.1.2 Amalgam and dental materials

Dental materials are used to repair damaged teeth or to replace lost teeth. Desirable properties are that they shall be harmless to both dental-care personnel and patients, durable, able to withstand strong chewing loads, and aesthetically acceptable. Amalgam is an alloy of mercury and other metals. Dental amalgam contains silver, tin and copper in addition to mercury. About half of amalgam, by weight, is mercury [Kemikalieinspektionen, 1996]. There are no complete statistics available from which to determine reliably how much amalgam is currently used. Estimates can be made from the quantities of amalgam products supplied to the Swedish market. Statistics on fillings from county councils and patient groups are another method used to estimate use.

Dental materials can be divided into materials used for direct and indirect techniques. In the case of direct techniques the material is introduced in a plastic

state and hardens in the tooth, while in indirect techniques an impression is usually made which is used by a dental technician to make an inlay or crown. The most common filling materials nowadays are different types of composite. Other materials used are ceramics, glass ionomer cement and cast metal (principally gold alloys and titanium). Also used are combinations of materials, e.g. "compomers". There are also prefabricated ceramic cones, which are pressed into composite fillings to reduce shrinkage of the filling. There is constant research into the development of new materials. One example is hydrated ceramics, which form a body-compatible substance that is integrated chemically and biologically into the tissue. These are not yet on the market.

According to the Swedish Dental Trade Association, there are six distributors of amalgam in the Swedish market and two companies that manufacture such materials. According to the Association there are currently no Swedish manufacturers of alternative filling materials producing for the Swedish market. The number of companies that distribute or supply alternatives to dental amalgam on the Swedish market is around forty. (Svedberg, personal communication)

6.1.3 Are there alternatives to amalgam?

In Sweden amalgam has been replaced to a large extent by other filling materials during the last five to six years. The quantities of mercury sold for amalgam are estimated to have decreased from 980 kg in 1997 to about 100 kg in 2003 (see Annex 3), which, in itself, indicates that the need for amalgam is not as great as formerly. During the investigation it has become clear that what has caused this reduction is, *inter alia*, a high awareness of the environmental and health risks among both patients and dentists, access to and demand for other alternatives, the agreement between the state and the county councils to phase out use in children and young people, and the abolition of financial support for amalgam fillings from the national dental insurance service.

According to a survey carried out in 2002 by Statistics Sweden (SCB) for the Dental Material Investigation [SOU 2003:53] 64% of the dentists questioned say that they do not use amalgam, while 36% do. Asked whether they consider that there are currently satisfactory alternatives to amalgam 61% answered "Yes" and 33% "No".

According to the National Board of Health and Welfare 2002 follow-up of the dental care of children and young people, the use of amalgam has decreased to about 0.1% of the total number of fillings (based on statistics from eight out of a total of 25 responsible authorities. Since 2003 the Board has tightened up its written advice that alternatives to amalgam must always be the first choice. Nevertheless if amalgam is considered the tooth's future importance for the biting function should be tested, since removal of the tooth can in certain cases be a better alternative than repairing it with amalgam. [Socialstyrelsen, 2002] The last follow-up survey for 2003 is based on data from 21 of 25 responsible authorities and shows that use has halved since 2002. Amalgam's share of fillings is stated to be only 0.05% of the total number of fillings in children and young people. A majority of the responsible authorities state that amalgam is no longer used at all in the case of children and young people [Socialstyrelsen, 2002].

The National Board of Health and Welfare has also followed up the use of amalgam in adult dental care within the Public Dental Service by means of a questionnaire sent to all the Service's County Dental Directors. The answers showed that the share of amalgam fillings was just under 3% of the total (2002) and it can no longer be regarded as the first choice as filling material [Socialstyrelsen, 2003]. The same year the Research Group for Community and Information Studies (FSI) carried out a questionnaire investigation for the Ministry of Health and Social Affairs and the Dental Material Investigation, which shows that around 18% of the patients questioned *believe* they had got amalgam fillings when they had had teeth repaired during the last two years [SOU 2003:53].

The results from these two investigations differ substantially. The time available for the present investigation has not permitted any clarification of which result is closer to the truth. The National Board of Health and Welfare follow-up of the use of amalgam within the Public Dental Service's adult dental care in 2003 [Socialstyrelsen, 2004] has however shown a further reduction of the share of amalgam fillings from just below 3% to 1.8% (data from 21 of 25 responsible authorities). According to the National Social Insurance Board (RFV) previous comparisons showed that the use of amalgam is similar in the Public Dental Service and in private dental care (Håkansson, personal communication). It therefore seems improbable that the use of amalgam in private dental care is currently significantly higher than in the Public Dental Service—enough for the total use to amount to 18%, as suggested by patients. From a rough estimate of the number of amalgam fillings calculated from the quantities of mercury sold for amalgam according to the Dental Trade Federation (about 100 kg) it appears that the figure of around 2% of the total number of fillings is too small and it should be around 5%²².

Treatment of patients with special needs

Amalgam continues to be used in the treatment of children and adults who are severely ill or suffering from grave physical and mental development disorders, the mentally ill, habitual criminals and people who are fearful of dentistry (Palmö, personal communication). These patients can for various reasons be hard to treat if they do not cooperate with dentistry staff to the extent necessary for dental treatment. In many cases this is therefore carried out under general anesthesia.

There are patients who for medical reasons cannot be anaesthetised, e.g. people who are seriously ill or have a high risk of complications [Tandläkarförbundet, 2004a]. Amalgam is used, exceptionally, for filling teeth if the patient requires protracted or extensive treatment and the dentist judges that treatment with amalgam will be quicker and less onerous for the patient than using alternative filling materials. In the case of very sick patients treatment with amalgam sometimes takes place in hospital wards and at the patient's home (Palmö, personal communication).

In the data submitted to KemI, treatment under general anesthesia has been highlighted by a number of the respondents as an area where amalgam will continue

²² Assume: A medium-sized three-surface amalgam filling = 0.6 g of mercury + 20% wastage. Thus 100 kg of mercury is enough for about 140,000 fillings. If half of these are supplied within the Public Dental Service this would correspond to 4.4% of the total number of fillings (1,583,988) provided by the Service in 2003.

to be needed because of difficulties in making durable composite fillings under these treatment conditions. The reason given by the majority of them is that it is difficult to maintain adequate dryness when working under general anesthesia, as is necessary when repairing with composites. Another reason given is that it takes longer to carry out repairs with filling materials other than amalgam. There are other respondents however that considers these problems can be handled, and that amalgam can be replaced by alternatives in every case.

Dental care under general anesthesia is performed principally by the hospital dental service but it also takes place at a few private clinics. The patients who need to be anaesthetised often need extensive treatment, which must be completed during the maximum of three hours of general anesthesia. Since general anesthesia can carry health risks, especially for patients who are already ill, attempts are made to minimize the number of episodes of general anesthesia and also their duration. According to the Swedish Association of Hospital Dentists the number of people who fear dentistry has increased in recent years and a high proportion of them are refugees and middle-aged women who need extensive intervention (Palmö, personal communication). Treatment by psychologists and psychotherapists is used in some cases to reduce the fear. At clinics that specialize in this, it is estimated that around a third of the patients are helped so that they can undergo treatment while awake (Friedner, personal communication). Tranquillisers are also used in some cases.

In the case of treatments under general anesthesia the patient is given oxygen and anaesthetic through tubes (intubation), as far as possible through the nose. There are some patients for whom this is difficult and intubation has to take place through the mouth, which means the working space for the dentist is more limited. This is the case, for example, with children and with adults where it is cramped and therefore there is increased risk of bleeding (Ekman and Palmö, personal communication). Sometimes there are other medical reasons for oral intubation. Irrespective of the intubation technique the throat must be blocked with gauze bandage, i.e. throat packing, to prevent material getting into the throat.

General anesthesia, in itself, causes the patient to have a reduced saliva secretion, corresponding to a sleep state. In addition to that, further measures are required to produce dryness in the mouth, which is conditional for making durable composite fillings. One alternative is to give medicine that prevent saliva production under anaesthesia and adrenalin-containing local anesthetics to reduce the risk of bleeding from the gums when the cavity to be repaired lies deep under the edge of the gum (deep under the gingival margin). Other alternatives to achieve dryness are suction, cotton rolls, rubber dams and astringents (medicines that have a contracting effect on the blood vessels).

There are clinics that never use amalgam. They mainly treat patients with dental fear, often with a very great need for dental treatment, under general anesthesia. They mainly use composite materials and the work takes about the same time as if the treatment had been carried out with amalgam (Friedner, personal communication). Plastic-reinforced glass ionomers are also used on surfaces that are not exposed to great stress, e.g. at the edges of gums. For patients who have difficulties in keeping their teeth clean it can be a good alternative for reducing the risk of secondary caries since glass ionomers release fluoride. Pure glass-ionomer cements are, however, not a good alternative in the case of treatments under general

anesthesia since they last for a maximum of two to three years, after which the operation must be repeated (Olsson, personal communication). Bridges and crowns must sometimes be made, irrespective of access to amalgam, which means extra episodes under anaesthetic for the patient

What differentiates amalgam from other dental materials used in the direct technique is that it solidifies by itself within a few days and does not need to be hardened. When using amalgam the dentist can immediately start work on the next tooth while composites, for example, need to be hardened with the lamp after each layer is applied. There are modern curing lamps for hardening composite fillings which, depending on the material and the thickness, harden a layer in 3 to 20 seconds. With only three seconds of hardening time there is however a risk that the filling is not hardened sufficiently if the lamp is not aimed optimally. This can lead to impairment of the mechanical properties of the filling [Umeå universitet, 2004].

According to the National Board of Health and Welfare (Ekman, personal communication) a well-made amalgam filling does not need to be polished but if it does it should be possible to do it without anaesthetising the patient again. Composite fillings can be polished directly after hardening but it is recommended that it should not be done for 24 hours [Kunskapscentrum för dentala material, 2004].

6.1.4 What would be the impacts of a ban?

Impacts on routine treatment

For normal dental care it is the judgement of KemI and the National Board of Health and Welfare that a ban on amalgam will not lead to any adverse effects on treatment. The analysis has shown that there are other filling materials on the market, which all in all replace the need for amalgam, and these are already used for 95-98% of all fillings.

Treatment of patients with special needs

The analysis has shown that there are possibilities for producing durable composite fillings under anaesthetic. This is already practised in certain clinics. A ban could however mean difficulties in treating sick patients if they take medicines that should not be combined with salivation-inhibiting drugs. Opinions about the extent of difficulties vary. According to the Specialist Clinic for Anaesthesia using suction, cottonrolls or rubber dams should be sufficient to maintain dryness (Friedner, personal communication). According to the Swedish Dental Association and the Association of Hospital Dentists these mechanical methods are not sufficient in some cases. A ban on the use of amalgam would therefore mean that in the case of these patients teeth would need to be extracted instead of repaired, which is regarded as unethical. This applies for example in situations where repairs need to be made on teeth far back in the mouth, the cavities are located below the edge of the gum, and drainage cannot be achieved because of severe bleeding from an inflamed gum [Tandläkarförbundet, 2004b]. Such situations can also arise when patients are not treated under general anesthesia. The Coordination Committee for the Swedish Disability Federation (HSO) considers that no exemption is needed for use in hospital dentistry since there are satisfactory replacement materials and there is no reason why these should not be used on their members [HSO, 2004].

For medical reasons some patients are intubated via the mouth instead of the nose. This means that the working space for the dentist is more limited, which makes the work more difficult. The Swedish Dental Association and the Association of Hospital Dentists maintain that it is necessary to use amalgam in these situations, while the Specialist Clinic for Anesthesia considers that the problems with oxygen tubes and the reduced space occur irrespective of whether amalgam or another filling material is used. In the case of children who are treated under general anesthesia and are intubated via the mouth filling materials other than amalgam are used to a large extent despite the limited space. But since the life of primary teeth is relatively short there is not the same requirement for the fillings to last as long as those in permanent teeth in adults (Ekman, personal communication).

According to the Association of Hospital Dentists the patients who need to be anaesthetised, often need extensive treatment that must be completed during the maximum of three hours of general anesthesia, and therefore time pressure comes into the picture. Here too, however, opinions differ between those who maintain that amalgam is absolutely necessary when many fillings have to be done and those who maintain that using alternative materials does not have to mean any significant lengthening of the period of anaesthesia. (See the analysis for patients with special needs, and impacts on the patient's health below.)

Impacts on health and the environment

Patient's health

All filling materials can give rise to hypersensitivity in susceptible persons. The Dental Material Investigation, [SOU 2003:53] observes that information about side effects from dental materials is inadequate and that their frequency is hard to establish, in part because of a lack of diagnostic methods. But since there are now so many materials to choose from the dentist can probably find the material that does not cause problems for the patient.

Amalgam corrodes and can consequently expand and split the teeth. This has been studied and confirmed using electron microscopy and photography. The risks of such impacts on the patients and the subsequent need for extensive treatment would decrease if a ban were introduced. The fact that a smaller quantity of healthy tooth-tissue needs to be removed when making repairs with materials other than amalgam is also beneficial for the patient.

The Association of Hospital Dentists points out, however, the risk of an increased problem with caries for patients with poor or non-existent oral hygiene since, for example, a composite filling can give a gap between tooth and filling and cannot be made as smooth as an amalgam filling (Palmö, personal communication) which means that the risk of caries in connection with the filling is greater. According to the International Academy of Oral Medicine (IAOMT), however, there is no problem with gaps in the case of a correctly performed composite filling. While there is always a gap between an amalgam filling and the tooth the environment there does not permit the growth of bacteria [IAOMT, 2004].

For patients treated under anaesthetic there are health risks, especially for those who are already ill, so that attempts are always made to minimise the use of general anesthesia and also its duration. The Swedish Dental Association and the Association of Hospital Dentists (Palmö, personal communication) fear that a ban

on amalgam would mean an increase in the number of episodes of general anesthesia per patient because for reasons of time it would not be possible to carry out all the repairs at one time. This is rejected, however, by the Specialist Clinic for Anaesthesia (Friedner, personal communication), whose patients are also reported to have a very great need for dental treatment, comparable with hospital dental-service patients. The Clinic maintains that a ban on amalgam would not mean an increase in the time required for treatment and thus in the number of episodes of general anesthesia in the normal case (see the analysis for patients with special needs). For certain patients with an extremely great need for treatment, however, a ban may mean some extra use of general anesthesia. These patients may, however, also be in need of other forms of dental treatment, e.g. crown therapy, which also gives rise to extra episodes of general anesthesia irrespective of access to amalgam.

For seriously ill patients who are treated within the hospital dental service and who for medical reasons cannot be anesthetized, the effects of a ban could be that the treatment takes longer and is more stressful, according to the Association of Hospital Dentists (Palmö, personal communication).

Health of dental personnel

In the mid-1990s there was an increase in the number of cases of skin damage and allergies among dental-care staff as a result of an increased use of various acrylic resin based composites and bonding materials used to fix composite fillings to teeth. Dental staff has now to a large extent learned to handle these products and the manufacturers have modified the packaging to reduce the risks. Data from the Swedish Information System for Occupational Accidents and Work-Related Diseases (ISA), show that skin injuries related to unpolymerized acrylic-resin based materials used in dental treatment have decreased from thirty-eight cases in the peak year of 1997 to five cases in 2000. In 2001 eleven cases were reported [Arbetsmiljöverket, 2001]. During the period 1997-99 the Work Environment Authority carried out an extensive inspection and information program covering the whole country. KemI inspected manufacturers and importers of dental filling materials because, *inter alia*, dentists had reported that it was difficult to get information about what alternative filling materials contain. One result from the inspections was that packaging, labelling and product information sheets were improved [Kemikalieinspektionen, 1997a].

Dentists and dental nurses would reduce their exposure to amalgam if a ban were introduced. A ban would not appreciably increase the risks of allergies from acrylic-resin based materials since these are already used to a great extent.

A ban on amalgam would also reduce the exposure of teachers and students in dental schools, where teaching about using amalgam is carried out using dummies.

Environmental impacts

A ban on the use of amalgam would mean that the new supply of mercury for amalgam fillings would cease. In 2003 the dental supplies industry estimated sales of mercury for amalgam in Sweden at about 100 kg.

The presence of mercury in sewage sludge makes it more difficult to use sludge as an agricultural fertilizer and thus to close the cycle of nutrients between town and country. Investigations of metal flows in Stockholm have shown that amalgam is the

largest single source of the mercury in the sludge. Almost half of this is mercury released from amalgam fillings, while they are in the mouth, and another large part comes from incomplete separation of amalgam from dental surgeries, including mercury in waste pipe sediment [Sörme and Lagerkvist, 2002; Sörme *et al*, 2003].

According to checks carried out by the Stockholm Water Company, there are deficiencies in the effectiveness of amalgam traps. In some cases they are installed incorrectly, blockages occur and they are often maintained inadequately. In a study carried out in 1998 one in four traps checked did not operate correctly, which could lead to increased discharges [Stockholm Vatten AB, 2000]. Estimates for Stockholm have shown that even if the traps' cleaning capacity were theoretically 95-99% then the amount of mercury discharged would correspond to 2-11% of the total quantity of pollution [Sörme, 2003].

A ban on the use of amalgam would lead to the release of mercury from dental clinics falling and in the long term ceasing. Despite a ban, however, amalgam will continue to be handled in dental surgeries for a number of years to come as old amalgam fillings are removed. Among the adult population 74% have amalgam in their mouths [SOU 2003:53]. The sewage treatment plants will also continue to be polluted with mercury from households since these fillings will continue to leak mercury during their lives. In the long term, however, a ban will reduce this pollution as well.

Crematoria are one of the largest sources of air emissions of mercury in Sweden. The Swedish EPA calculated emissions from crematoria as 123 kg of mercury in 2001. In Sweden 70% of the dead are cremated and just over half of cremations take place with flue-gas scrubbing [Naturvårdsverket, 2004a]. In these cases a mercury-containing scrubbing product is produced which must be dealt with for final disposal.

If the use of amalgam were banned then in the long-term mercury emissions from crematoria would in principle cease. If more people underwent amalgam removal, mercury emissions from crematoria would fall more quickly and so would household discharges of mercury to sewage treatment plants. Amalgam removal can, however, mean health risks for the individual patient and a risk of mercury release from the dentist's surgery.

To summarise, a ban on amalgam would mean that one of the largest remaining areas of use of mercury would cease. The use of amalgam leads to atmospheric emissions of mercury, discharges to sewage treatment plants and clean-up products that must be processed for final disposal. A ban is necessary to ensure that, in the long term, these releases of mercury into the environment cease.

Economic impacts

Dental clinics

According to the Swedish Federation of County Councils (FCC), the decisive factors for the costs of dental clinics and their pricing of dental treatments are premises rental, salaries, treatment time, etc. [Landstingsförbundet, 2004]. According to information from the Specialist Clinic for Anaesthesia (Friedner, personal communication), and the Biomedical Dental Centre, material costs for fillings contribute about 5-10% of the treatment costs, irrespective of the type of

material (Olsson, personal communication). According to a report from the FCC, salary costs amount to almost three-quarters of the total costs of the National Dental Service [Landstingsförbundet, 2004].

The National Dental Service in Västernorrland points out that the purchase costs for, *inter alia*, composite materials are higher than for amalgam and that an increased demand for alternatives has not meant a price reduction from the suppliers [Folktandvården i Västernorrland, 2004].

For dental clinics that work with treatments under general anesthesia and do not already have an efficient lamp for light-curing of composite fillings, a ban on amalgam implies a capital cost for new equipment. KemI judges that costs for new equipment do not imply any adverse effects when the prices of new curing lamps lie in the range SEK 5,000 – 15,000 (544 – 1,633 EURO).

Patient costs

Since 1 January 1999 patient fees are no longer regulated by the Government, which means that prices can vary greatly between dentists. It is therefore difficult to obtain comparable information. Free pricing can be of greater importance for the patient's finances than the choice of filling material. Each county council determines the National Dental Service prices and they therefore vary between counties. Private care-givers determine their own prices.

The patient's reimbursement for dental care has not been adjusted since prices were decontrolled. Each change in the caregiver's charges has therefore impacted directly on patient charges. An exception is high-cost protection for patients aged 65 or over, which came into force on 1 July 2002. Up to 1 January 1999 the patient met the costs of all dental care up to SEK 1,300 (142 EURO). For costs above this, the dental insurance paid out a dental-care grant according to a fixed percentage depending on the amount.

Since 1999 the patient gets no reimbursement from the dental insurance for amalgam fillings. The result is that the costs to the patient for an amalgam filling are as much as for a repair with composite, or even more. According to Uppsala County Council's 2004 price-list for general dental care the patient's fee for single-surface fillings with materials other than amalgam is SEK 484 (53 EURO) [Landstinget Uppsala län, 2004]. According to the Public Dental Service 2004 prices for general dental care the price for single-surface fillings with amalgam varied between SEK 313 (53 EURO) and SEK 610 (66 EURO). The corresponding price-range for single-surface fillings with other materials was SEK 358 – 625 (39 – 68 EURO). From this, the price differences between materials do not seem to be so large: the price differences between county councils and private dental clinics are of greater importance.

Where larger repairs and crowns are concerned the patient's fee can, for example, vary between SEK 985 (107 EURO) and SEK 1,200 (131 EURO) for amalgam crowns. The corresponding fee for a composite crown can be SEK 950 – 1,462 (103 – 159 EURO) [Uppsala County Council, 2004]. The price depends partly on the difficulty but also on which surgery or region the treatment is carried out in. The Public Dental Service in Västernorrland points out that treatment costs with, for example, composite materials is higher than for amalgam and the increased demand

for alternatives has not meant any price-reduction from the suppliers. For the patient it is, according to these dentists, still cheaper to have an amalgam crown than, for example, a gold or porcelain crown [Folktandvården i Västernorrland, 2004]. The National Social Insurance Board (RFV) states that the price of a gold or porcelain crown varies between about SEK 3,300 (359 EURO) and SEK 4,500 (490 EURO). On top of this is the cost of materials, which for gold is about SEK 400 (44 EURO) per crown. Where a pillar must be manufactured there is a further cost of about SEK 1,500 (163 EURO) (Håkansson, personal communication).

For patients with financial difficulties the impacts of a ban on amalgam can become apparent if the only alternative to a new gold or porcelain crown is to extract the tooth. In the National Board of Health and Welfare follow-up of the use of amalgam in the Public Dental Service in 2003, the dental-care trustees reported that it was often older patients who were affected—people who already had extensive amalgam repairs and regarded themselves as unable to afford crown therapy [Landstingsförbundet, 2004].

According to the RFV analysis of the price trend for dental care over the period 2000-2002, patients' costs have increased since the introduction of free pricing, and prices continue to rise [Riksförsäkringsverket, 2003]. According to the Board, the county councils raised patients' fees by 16-27% on average over the period May 2000 to December 2002, depending on the particular treatment. According to the Federation of County Councils, prices for public dental care over the country as a whole have increased by 5.3% between 2003 and 2004. Between 1998 and 2003 they increased by 59.8%. Amalgam fillings are among the items for which the price increase has been highest over the period 1998 to 2004. Between 2003 and 2004 the price of one-surface amalgam fillings rose by 12.1%. The corresponding increase for equivalent composite fillings was 2.8% [Landstingsförbundet, 2004].

According to the County Councils the price increase has been necessary to improve the working environment of dental personnel within the Public Dental Service. A further contributing factor is dentists' salaries, which have increased substantially over this period because of competition from abroad [Landstingsförbundet, 2004].

The Board's investigation shows there are large differences between county councils. For private dental care patient fees have on average increased by 6-27% over the period October-December 2002, depending on the treatment. Patient fees for private care also differ between counties [Riksförsäkringsverket, 2003].

The price difference between the private sector and the county councils is small but in most cases average private-sector prices are above those of the county councils. The RFV study also shows that within the private sector prices for fillings are increasing more than for preventive treatment and examination. Its analysis also shows that patient fees for dental care have increased more rapidly than the general trend in prices, which was up by 5% over the same period [Riksförsäkringsverket, 2003].

According to the RFV analysis, 60% of the people questioned say that they would not change dentists even if there were a cheaper dentist within a reasonable distance. According to the investigation it is not primarily the price that is critical for whether the patient continues to see the same dentist. More important considerations are confidence in the dentist and the service provided [Riksförsäkringsverket, 2003].

The choice of standards and materials affects the price. The patient can choose between the different filling-materials. The person providing the care has a great influence on the choice of material since the patient normally finds it hard to judge the need for and extent of treatment himself. According to an analysis by RFV about 78% of the respondents said that they let the dentist or dental hygienist do everything they suggested. Since oral health and the choice of treatment is an individual matter it was not possible in the study to give an opinion about the relationship between price and standard and about whether the price variations which occurred were reasonable or not [Riksförsäkringsverket, 2002].

Keml's judgement is that patient costs will not be affected adversely by a ban on amalgam. Decontrol of pricing in dentistry has already brought with it effects on patient costs and for the great majority of patients a ban will not entail any further impacts. For patients with financial difficulties the impacts can be significant if amalgam is not available and the choice is therefore between a new gold or porcelain crown and extraction of the tooth. It ought, however to be possible to limit such adverse effects within the framework of the dental insurance scheme and they should not prevent a ban on amalgam.

Swedish dental trade

According to information from Nordiska Dental AB, which manufactures and markets dental filling materials, an exemption for amalgam from the general ban on mercury is a prerequisite for the continued development of new products and their marketing in those markets where the company currently sells amalgam [Nordiska Dental, 2004].

The 2-5% of fillings that are currently provided using amalgam can almost entirely be replaced by other materials. Keml's judgement is that a ban on amalgam in Sweden would not imply any extensive adverse financial impacts on companies affected.

Research and Development

The analysis has shown that the commonest dental-filling materials today are composites and that these and other materials have to a large extent replaced the use of amalgam. Research and development are continuing to find even better materials. A ban on amalgam in Sweden would probably have no great effect on this development since the use of amalgam is already relatively marginal and the market for other materials would therefore not be affected very greatly.

Training of dentists

Nowadays, students in the country's dental schools are first taught about other materials for oral reconstruction. Teaching about amalgam forms only a small part of the training of dental students and is mostly theoretical. A ban on the use of amalgam would according to the dental schools mean that training would be affected adversely. Swedish dental students would not be able to learn practically how to carry out amalgam fillings, which could affect their opportunities to seek work abroad and to have their qualifications approved in other countries. Each year about 10% of students make their way abroad after completing training in Sweden.

For students who train as dentists the cost of further training so that they can also carry out amalgam fillings could be an extra expense if they want to work abroad.

6.1.5 Conclusion

Although the use of amalgam has decreased considerably during the last few years, just over 100 kg of mercury is still used in dentistry each year according to the Swedish Dental Trade Association. This is mercury that ends up in the natural environment in one way or another. Using amalgam requires emission control measures to prevent releases of mercury. These measures produce hazardous waste that has to be finally disposed of. Even though emission control is used, mercury will contaminate the sewage sludge and emit to the air from crematoria.

There are therefore strong reasons from an environmental point of view to prohibit the use of amalgam. From a health point of view there is every reason to apply a precautionary approach. There are other tooth-filling materials available on the market. These meet existing needs and could replace the whole remaining use of amalgam within ordinary dental care for children and adults.

There are different views, however, as to whether other filling materials on the market can replace amalgam in all the treatment situations that occur in hospital dentistry. The judgement of the National Board of Health and Welfare is that there is no justification for any exemptions for amalgam in the case of children and young people. But there may be a few situations where for special medical reasons the use of amalgam on adult patients in hospitals is the only alternative to extracting the tooth, which in some cases may be regarded as unethical. It is unclear how large this use is today but it is estimated that it is at most 20% of the use of amalgam, corresponding to about 20 kg of mercury per annum. A three-year exemption from the general ban is judged to be a reasonable time.

A special obligation for the dentist performing the treatment to keep records is necessary in order to get a better knowledge base concerning the need for and extent of amalgam use before future follow-ups of its use in hospital dentistry. It cannot be regarded as reasonable to use amalgam on hospital wards or in the course of home visits where there is no adequate equipment to protect health and the environment since there are other filling materials which can be used in acute situations.

In KemI's judgement costs for patients will not be affected adversely by a ban on amalgam. The decontrol of pricing within dentistry has already brought about effects on patient costs and for the great majority of patients a ban will not mean any further impacts. For patients with financial difficulties the impacts may be significant if the choice is between making a new gold or porcelain crown and extracting the tooth. It ought however to be possible to limit such adverse effects within the framework of the dental insurance scheme and they should not prevent a ban on amalgam.

The 2-5% of fillings that are currently carried out using amalgam can be replaced almost totally by other materials. KemI judges that a ban on amalgam in Sweden should not mean any extensive adverse financial impacts for the companies concerned.

Because the use of amalgam is to cease in Sweden it cannot be regarded as reasonable to grant a general exemption for the use of amalgam in the training of

dentists. Sweden is working for corresponding restrictions on amalgam within the EU and internationally. If there is found to be exceptional problems for the about 10% of students who find their way abroad the dental schools will be able to apply for a dispensation to provide further training.

6.1.6 Proposal

Dental amalgam should be covered by a general national ban.

KemI and the National Board of Health and Welfare consider, however, that dental amalgam should be exempted from the general ban until 31 December 2008 for use within hospital dentistry on adult patients where for special medical reasons other methods of treatment cannot be used with a sufficiently good result. Treatment with amalgam should only take place in dental clinics.

KemI and the National Board of Health and Welfare further consider that a special obligation should be introduced for the dentist performing the treatment to keep records. The reasons why other relevant methods of treatment could not be used should be stated in every case. A follow-up of the use of dental amalgam should be carried out one year after the ban comes into force.

6.2 Analytical chemicals and reagents

KemI estimates that the quantities of mercury compounds used in the form of analytical chemicals in Sweden in 2003 correspond to about 53 kg of mercury (see Annex 3).

Most of the mercury compounds used as analytical chemicals are classified as very toxic (see Para 3.4) and are therefore extremely dangerous products according to KIFS 1998:8, Chapter 8. Companies that distribute products that are extremely dangerous must have authorization from the county administrative board. The chemicals may only be transferred to a person who will use them professionally²³.

The impact assessment for analytical chemicals and reagents is based principally on about 40 questionnaire responses from accredited laboratories, industry organisations, individual companies in different industries, and suppliers of analytical chemicals, public authorities, hospitals and universities. Two consultation meetings have also been held. The industries represented are dyestuffs and pigments, sewage treatment plants, foodstuffs, medicinal products, medical diagnostics, the steel and non-ferrous metal industries, forest products and specialist chemicals. The focus in the impact assessment is on the industries whose responses indicated problems. In Sweden there are about 230 laboratories accredited for chemical analysis and about 110 for medical analysis according to SWEDAC, the Swedish Board for Accreditation and Conformity Assessment (SWEDAC's web site). The accredited are in some cases commercial laboratories which sell analytical services and in others part of a company which manufactures and/or sells products of some type. The commercial analytical laboratories may be part of concerns with operations in several locations throughout the country, each of which is accredited. In addition there are believed to be a number of laboratories that are not accredited. For this reason, among others, it has been difficult to establish how many potential

²³ Ordinance 1998:941, Sections 14-19.

areas of use and users of mercury and mercury compounds for analysis there are in Sweden.

6.2.1 Impacts on the environment and health

The use of mercury compounds as analytical chemicals represents a relatively large part of the current use of mercury and can cause substantial adverse impacts on the environment and health. When analyses are carried out in open systems there is a risk that the people who handle the chemicals are exposed to mercury. A certain amount of mercury risks ending up in the sewer system, even if there are internal water-treatment systems. The use of mercury compounds as analytical chemicals can thus make it difficult to use sewage sludge as an agricultural fertilizer.

In the case of analysis in both open and closed systems (e.g. vials) waste of various kinds arises—the sample analysed, the reagent solution used and the reference solution to which mercury has been added. This waste must be collected up, treated and sent for final disposal. A ban on the use of mercury as an analytical chemical would reduce direct occupational exposure and direct and indirect discharges to the natural environment as well as decreasing the quantities of mercury-containing waste.

6.2.2 Mercury analysis

Mercury analysis is needed in many situations. Within the environmental field there are methods for the determination of mercury in the air, water, soil, sewage sludge and waste. Mercury levels are also measured in blood, hair and saliva. In many branches of industry there is a need to carry out determinations of mercury levels in, for example, foodstuffs, steel and medicinal products.

Are there alternatives to mercury?

There are no alternatives to using mercury or mercury compounds when analysing for mercury. To be able to analyse for mercury and mercury compounds access is needed to reference solutions with known concentrations of mercury compounds.

What would be the impacts of a ban?

A ban would mean that measuring and reporting mercury levels would be impossible. This would affect both national and international monitoring work and Sweden's cooperation with and contribution to the latter. Monitoring programmes could therefore not be carried out and reports to, for example, international conventions could no longer be compiled. Furthermore, food and medicinal-product companies could no longer ensure that their products meet the limits laid down.

Conclusion

A general exemption for analysis for mercury and mercury compounds is required. It is not possible to time-limit the exemption because mercury will always need to be monitored as regards its occurrence and residue levels. A ban would mean that it would be impossible to carry out the measurement and reporting of mercury levels.

Proposal

KemI considers that the use of mercury in analysis for mercury should be exempted from the general ban with no time limit.

6.2.3 Chemical Oxygen Demand (COD)

Chemical Oxygen Demand (COD) is a measure of the theoretical oxygen consumption of a water sample. The organic matter in the sample is oxidised chemically with potassium dichromate, COD_{Cr}, or potassium permanganate, COD_{Mn}, to calculate how much oxygen is needed to break down the organic matter. When analysing COD using potassium dichromate as the oxidising agent, mercuric sulphate is added to precipitate chloride ions, which otherwise interfere with the analysis and make the value measured too high.

According to the standard method (SS 02 81 42) COD is analysed using a wet-chemical method and 400 mg of mercuric sulphate is added to precipitate chloride ions. There are also commercial vials that are used in a standard ISO method [ISO 15705]. The analysis is carried out in a closed tube containing a very small quantity of mercuric sulphate (about 40 mg). Vials without mercuric sulphate can also be purchased. All the questionnaires returned stated that the vial method for COD is used.

The quantities of mercury compounds in analytical chemicals are estimated by KemI to have been equivalent to about 53 kg of mercury in 2003, see Annex 3. Use for COD analyses in vials represents about 14 kg or just over 25%. COD analyses are therefore the single largest application for mercury compounds within chemical analysis, which it was possible to identify in the investigation.

Background

It has long been discussed whether COD can be replaced by another parameter, total organic carbon (TOC). Since the 1970s the Swedish Environmental Protection Agency (SEPA) has been working to reduce the use of COD analyses in Sweden and measure TOC instead [Naturvårdsverket, 2004b]. The last time the question was investigated was in 1999 in collaboration between KemI and SEPA. Then, too, it was recorded that COD was the largest single application of mercury in chemical analysis. Work on a voluntary reduction in the use of mercury-containing analytical chemicals and reagents was regarded as having gone too slowly and a ban was seen as the only practicable method for bringing about a reduction (see Para 2.3).

Many industries measure COD in their process water and in water discharged from their plants, e.g. pulp and paper mills, effluent treatment plants, the chemical process industry and the food industry. Activities that require authorization under the Swedish Environmental Code have conditions imposed as to what they may discharge into the receiving body of water. The conditions can be set as COD, BOD₇ (biochemical oxygen consumption, 7 days) or both. A few of the enterprises concerned have the parameter TOC in their discharge conditions. (Naturvårdsverket, 2004b).

Are there alternatives to mercury?

Three alternatives to COD using mercuric sulphate emerged from the investigation—COD without the addition of mercuric sulphate, TOC and BOD. It is possible to measure COD without adding mercuric sulphate if the sample does not contain too many chloride ions. There are commercially available COD vials without mercuric sulphate which, according to the manufacturer, can be used in the range 100-1000 mg/l of COD if the chloride content does not exceed half the COD value, Benito and Morrison (2003) have developed a mercury-free COD method using silver nitrate instead of mercuric sulphate. The method has mainly been tested on municipal effluent. Since the method is new and relatively untested it is hard to judge whether it constitutes a real alternative to COD using mercuric sulphate.

COD can also be determined using potassium permanganate as the oxidising agent: in this case mercuric sulphate is not added. This analysis is often designated COD_{Mn} or permanganate number and is suitable for measurements on water with a low content of organic matter, such as lake water, since the detection limit is lower than for COD with potassium dichromate [Naturvårdsverket, 2004b].

TOC gives a measure of the quantity of organically bound carbon in the sample, both dissolved and in the form of particles. The analysis is sensitive to particles in the sample and the sample can then be filtered before analysis. If filtration is carried out before analysis of TOC only the fraction of the organic matter dissolved in the water is measured. This analysis is often called Dissolved Organic Carbon (DOC) [Naturvårdsverket, 2004b].

Biochemical oxygen demand (BOD) is an analytical method that measures the quantity of oxygen consumed bio-chemically under controlled conditions in a specified time. In the case of 20°C and 7 days the method is designated BOD₇. BOD₇ gives a measure of the fraction of easily degradable organic matter. The drawback to BOD₇ is that it takes a comparatively long time, 7 days, before the results are obtained [Naturvårdsverket, 2004b].

It is possible to make correlations between COD and TOC by measuring the parameters in parallel over a period. Many investigations have been made of the correlation between COD and TOC [Naturvårdsverket, 2004b]. These show that a good correlation is often found. It is then possible to establish a factor for converting TOC values to COD when COD must be reported. There are also cases that show a very poor correlation so that no correlation factor can be established. There are examples of enterprises which have authorization conditions the idea of which is to investigate the correlation between COD and TOC in order later to switch to TOC after consultation with the body issuing the authorization [Naturvårdsverket, 2004b].

There are about 60 pulp and paper mills in Sweden that are members of the industry organisation Skogsindustrierna. About a quarter of the mills are positive about using TOC instead of COD and some of them are considering going over to TOC. Some have tested the mercury-free COD method but for the majority it does not work because of interference from chloride ions. The correlation between COD and TOC is in many cases not satisfactory and must be established for each sub-flow in the process. Around two-thirds of the pulp and paper mills consider that they need to retain COD analysis using mercury (Haglund, personal communication).

The Waste Water Directive [91/271/EEC]²⁴ states that COD must be measured but not that the method using mercuric sulphate must be used. According to the Directive it is possible to replace the stated analytical methods with alternatives if it can be shown that they are as good. Germany has already got a national exemption from measuring COD but has still not introduced TOC into its regulations. It is however possible to calculate the COD value from the TOC value and in those cases where a conversion factor cannot be established the enterprise can have its conditions reconsidered by the body issuing the authorization [Naturvårdsverket, 2004b].

Measurements of COD in urban waste water are made to control the treatment processes, to monitor discharges and to characterize the waste water. Some sewage treatment plants have begun to move away from COD. From 1 April 2004 Stockholm Water Company will start to measure TOC instead of COD (Lindblom, personal communication). Other sewage treatment plants are investigating the possibility of moving away from COD analysis, among them Malmö and Örebro (Lind, personal communication). Characterization of waste water is carried out in order to see the effect of industrial waste water in the urban waste water. In this characterization it can be difficult to replace COD; it is possible that TOC, for example, can be used for this as well but further investigations would be needed to demonstrate the possibility (Lind, personal communication).

A small number of questionnaires were returned by companies engaged in the production of dyes and pigments and of specialist chemicals. These currently use COD for measurements on the process streams and for discharge monitoring. The companies have carried out or have plans under way to replace COD with TOC and their returned questionnaires show that in certain cases there are possibilities of switching to TOC. It is hard to draw any general conclusions from such limited data but it appears possible to switch to TOC after investigating the correlation between COD and TOC.

In the food industry it is planned to investigate alternatives to COD during 2004. The amount of information in the questionnaire responses is small, however, so it is hard to draw any general conclusions about the possibilities for moving away from COD.

To summarize, it appears that extensive work is going on among the companies surveyed which is aimed at replacing COD with alternatives, principally TOC. A switch from COD to TOC requires a certain amount of investigation of the correlation between the two parameters and, if possible, the establishment of a conversion factor if COD is to be calculated from a TOC value.

What would be the impacts of a ban?

Commercial impacts

The analysis of the commercial impacts of a ban deals with five different types of company, i.e. suppliers of analytical chemicals, suppliers of alternative analytical

²⁴ Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment.

instruments (TOC), users of analytical chemicals in their own laboratories, users who send samples to outside laboratories, and those outside laboratories themselves.

An obvious impact of a ban would be that sales of mercuric sulphate and commercial vials containing it would fall while sales of TOC instruments would rise. The suppliers of analytical chemicals have not indicated that the reduced sales would lead to any significant financial loss. As far as KemI can judge, the (Swedish) market for chemicals for COD analysis contributes only a minor share of their revenues. On the other hand it is KemI's judgement that the positive impacts on manufacturers of TOC instruments would also be marginal, since the Swedish market will continue to be small from a European and international perspective.

For smaller companies, which already send their samples to outside laboratories, a national ban implies no change, since the cost of an outside TOC analysis is comparable with COD²⁵. The analysis of commercial impacts can therefore be restricted to users with their own laboratories and laboratory companies.

The costs the companies can incur are primarily the capital costs of the TOC instrument itself. There are in addition the costs of switching over, e.g. training/recruiting staff and establishing the correlation with COD. These costs fall largely on the user.

A switch to an alternative methodology means a capital cost for a TOC instrument, for example, of about SEK 400,000 (43,541 EURO). This may be regarded by the laboratory, depending on its size and turnover, as far too high a cost.

In a number of the questionnaire responses it was stated that the capital costs for TOC would be an obstacle to switching from COD. The responses give no clear picture of how many users have already switched to alternative methods. Some have already switched while others express an intention to do so.

According to the questionnaire responses, when the TOC method is in operation it can be a quick, simple and economical method to use in large laboratories that have experience of instruments and which analyse at least 1000 samples per annum. KemI judges that the same applies to larger companies performing their own analyses.

The possibility of purchasing their own equipment for TOC analyses can be more limited for smaller laboratories and companies. SEPA, however, considers that the commercial impacts on individual companies as a result of reduced use of COD analyses using added mercury should be limited. This is because the cost of carrying out COD analyses at an authorized laboratory is about the same as for TOC analyses [Naturvårdsverket, 2004b].

An important difference between COD analysis using mercuric sulphate and TOC is that no hazardous waste is formed in the case of the TOC analysis. Over and above

²⁵ According to the price information collected, the cost of a COD analysis is about SEK 160 – 245 (17-27 EURO) and of a TOC analysis SEK 180 – 240 (20-26 EURO).

the cost of purchasing analytical chemicals, dealing with the waste is a significant item in the case of COD analysis²⁶.

To summarise, it is the judgement of KemI that the cost of switching to TOC instruments will in the long term be compensated for by the lower running costs and elimination of the costs of dealing with hazardous waste.

Impacts on discharge monitoring and process control

For companies which use COD analysis for monitoring the water they discharge and for process control the financial impacts can be adverse in the short term if the capital cost of TOC instruments is regarded as too high in relation to the business's turnover. An alternative, which remains for smaller companies that may be affected by this, is to employ outside laboratories. However, according to the suppliers of mercury-containing COD vials this can mean that the control of, for example, water-treatment processes and manufacturing processes is made more difficult since it takes longer to get the results. This in turn could mean adverse effects on the environment. The companies affected have not, however, quantified these possible effects. SEPA has not identified any such impacts in its survey of COD analysis [Naturvårdsverket, 2004b].

Impacts on national and international reporting of mercury levels

One adverse consequence could be that the national compilation of data on discharges from individual enterprises, industries and regions that are currently obtained using COD analyses is made more difficult. A national ban could also create impacts on ongoing work on comparisons of discharges indifferent countries. Currently COD values are used in such comparisons. It is however possible to calculate the COD value from a TOC value when a correlation factor has been established.

The impacts from a national ban on mercury would be that certain international standards (for more information on standards see Chapter 5: Standard methods) and Swedish rules such as SEPA's regulations concerning the treatment of urban waste water [SNFS 1994:7] would need to be altered or modified. SEPA is currently carrying out a review of SNFS 1994:7 but does not intend to change the requirement for COD analysis at the present time [Naturvårdsverket, 2004b].

Conclusion

The conclusion is that from a technical point of view there are in most cases alternatives to the analysis of COD using mercuric sulphate. A study of the questionnaire responses shows that a switch to alternatives to COD is under way in many enterprises while in others the development has not got as far. KemI notes that for larger laboratories and enterprises responsible for discharging water a switch to TOC can be positive from many aspects. On the other hand switching from COD to other alternatives produces temporary adverse impacts in the form of costs for investment and development work, especially for smaller enterprises.

²⁶ According to SAKAB's price-list the cost of dealing with COD vials is SEK 126/kg (14 EURO/kg). For "mercury-containing fine chemicals" (which includes COD analysis using wet chemistry) the cost is SEK 206/kg (22 EURO/kg).

To ensure that the switch to alternative methods can occur in commercially acceptable ways even for smaller enterprises it is necessary to have a time-limited exemption from the general ban. KemI judges that a three-year transitional period from the date when the ordinance and regulation come into force is adequate for replacing COD with an alternative method of analysis.

Proposal

Mercury compounds for COD analysis should be covered by a general national ban.

KemI considers, however, that mercury compounds for COD analysis should be granted a time-limited exemption from the ban and be allowed to be marketed until 31 December 2007 and used until 31 December 2008.

6.2.4 Foodstuff analyses

Mercury analyses are carried out in the foodstuff sector and most of the methods used are standardised. There are limits for mercury in, among other things, fish, baby food made from fish products [SLVFS 1993:36], drinking water [SLVFS 2001:30] and chemicals used for purifying drinking water. Mercury analysis is dealt with in Para 6.2.2.

There are also analyses that involve reagents containing mercury compounds. An example is the determination of *Pseudomonas aeruginosa* where Nessler's reagent is used for confirmation. Nessler's reagent contains potassium tetraiodomercurate corresponding to 0.5-0.7% of elementary mercury. The method is a European standard [EN SS 12789], which is in the process of becoming an ISO standard. The standard is incorporated in the Drinking Water Directive [98/83/EC] that has been embodied in Swedish legislation via the National Food Administration's (NFA) Drinking Water Regulation [SLVFS 2001:30]. The analysis has to be carried out only on drinking water sold in containers, but not on mineral water which is regulated by a different directive. Since the standard has only just come into use it is difficult to know how much use of Nessler's reagent this gives rise to.

Are there alternatives to mercury?

According to the NFA, when the standard for *Pseudomonas aeruginosa* was produced, Sweden raised the problem of the use of Nessler's reagent but did not receive support for developing any alternative. There is currently no alternative to Nessler's reagent in this case.

What would be the impacts of a ban?

The determination of *Pseudomonas aeruginosa* could not be carried out and therefore the requirements of the Drinking Water Directive could not be met.

Conclusions

The use of mercury compounds in analytical methods should be eliminated in the long term where that is possible. A time-limited exemption would provide the possibility of developing alternatives to Nessler's reagent. KemI judges that a period of three years from the date on which the ordinance and regulation come into force is a reasonable transitional period.

Proposal

Mercury compounds for foodstuff analysis should be covered by a general national ban.

KemI considers, however, that mercury compounds for foodstuff analysis should be granted a time-limited exemption from the ban and covered by the exemption for other analysis (Para 6.2.8).

6.2.5 Analysis in the medicinal products sector

In the medicinal products sector there are special standardised analytical methods for products, raw materials, etc. In two EC Directives (2001/82/EC and 2001/83/EC) there are requirements that substances used as medicinal products in the European market shall meet the requirements of the European Pharmacopoeia, which means that they must be analysed by the methods described there. The European Pharmacopoeia is incorporated continuously into Swedish law via statutory orders made by the Medical Products Agency (MPA) concerning the coming into force of Swedish standards for medicinal products.

MPA has counted up how many analytical methods in the European Pharmacopoeia involve the use of mercury compounds as reagents. The total is around thirty. They relate mainly to the determination of the mercury content of various medicinal products and raw materials, but mercury compounds are also used in other types of analysis.

Are there alternatives to mercury?

MPA is working to eliminate analytical methods in the European Pharmacopoeia which involve the use of mercury and mercury compounds. Since 1999 a number of methods have been replaced by mercury-free alternatives, mainly titrimetric methods in which mercury acetate is used as a reagent.

What would be the impacts of a ban?

Swedish medicinal-product companies would not be able to use analytical methods in the European Pharmacopoeia and could therefore not satisfy the Medicinal Products Directive.

A positive effect, however, is that a national ban on mercury will mean that Swedish representatives can propose changes to standards in the European Pharmacopoeia with greater force.

Conclusions

Analyses of mercury according to methods in pharmacopoeias will be needed even in the future. It is not possible to time-limit the exemption since mercury is an element which will always need to be monitored as regards its occurrence and residue levels. Therefore mercury analysis should be exempted from the general ban (see Para 6.2.2).

In the long term the use of mercury compounds in other analytical methods should be eliminated where possible. A transitional period is needed to develop alternative methods without mercury. The Medical Products Agency (MPA) judges that it can take up to seven years to develop a new analytical method and introduce it into the

European Pharmacopoeia. A period of seven years from the date when the ordinance and regulation come into force would therefore be reasonable.

Proposal

Mercury compounds for analyses in the medicinal products sector should be covered by a general national ban.

KemI considers, however, that mercury compounds for use in analyses in accordance with international standard methods in the medicinal products sector should be granted a time-limited exemption from the ban and be allowed to be marketed until 31 December 2011 and used until 31 December 2012.

6.2.6 Analyses for medical diagnosis

For certain medical diagnoses analyses are currently required in which mercury and mercury compounds cannot be replaced. Some examples have been included in the survey questionnaires but there may be many more diagnoses that involve mercury or mercury compounds. The analyses described below are not covered by the In Vitro Diagnostic Directive [98/79/EC].

The Porphyria Centre at the Karolinska University Hospital, Huddinge, uses sodium amalgam for enzyme analyses in the investigation of porphyrias. Porphyrias are a group of inherited diseases which arise from a lack of some of the enzymes which participate in the synthesis of haem, which forms part of haemoglobin. The analyses are necessary to make a correct diagnosis. The Porphyria Centre is the only clinic in Sweden that carries out these analyses and the annual consumption of sodium amalgam is about 25 g. Extensive work has been carried out for two years to replace enzyme diagnostics by detecting instead the genetic defect (JAF: Defective gene?) that produces the disease. This has not been successful and the clinic currently sees no alternative to the use of sodium amalgam.

At the same clinic the enzyme ALAD (5-aminolaevulinic acid hydratase) is analysed in the case of very rare investigations of porphyria caused by a lack of this enzyme and when there is a suspicion of blood poisoning. The analysis uses mercuric chloride—about 30 g per annum. There are no alternative methods of analysis. However, the number of ALAD analyses has decreased because they are no longer carried out routinely in the investigation of porphyria.

The Centre for Inherited Metabolic Diseases at the Karolinska University Hospital is currently investigating whether screening for Type I tyrosinaemia should be carried out on all new-born babies along with the PKU test. Tyrosinaemia is a group of rare metabolic diseases in children. The PKU test analyses specific enzymes and hormones to detect certain serious inherited diseases, including phenylketonuria (PKU). Expansion of the analyses in the PKU test would mean that an analysis using mercuric chloride would be used and consume about 60 g of mercuric chloride per annum for all the new-born babies in Sweden.

Are there alternatives to mercury?

For the diagnoses described above there are currently no alternatives. A certain amount of development work has already been carried out and in KemI's judgement more time is needed to develop alternative methods without mercury compounds.

What would be the impacts of a ban?

Patients with some diagnoses would not be properly investigated because the laboratory results would not be available. The impacts would be adverse for both patient and medical staff if a diagnosis could no longer be made. If mercury were banned certain diseases and conditions could no longer be investigated.

Conclusions

At the present time there are no alternatives to certain analyses used in medical diagnostics. In the event of a ban on mercury patients would not, in the case of certain diagnoses, be investigated because the laboratory results would not be available. A transitional period is required to develop alternatives.

In KemI's judgement a period of three years from the date on which the ordinance and regulation come into force is a reasonable transitional period.

Proposal

Mercury compounds for analyses in medical diagnostics should be covered by a general national ban.

KemI considers, however, that mercury and mercury compounds for use in analysis and research and development in medical diagnostics should be granted a time-limited exemption from the ban and be allowed to be marketed until 31 December 2007 and used until 31 December 2008.

6.2.7 Other analytical uses

The areas of use for analytical chemicals reported above are those which it has been possible to identify within the scope of the present investigation. There are probably a number of other smaller areas of use which have not yet been identified and for which it has not been possible to carry out an impact assessment. Despite this KemI judges that there are reasons to introduce a further time-limited exemption for three years for analyses other than those specified in the impact assessment. The greatest advantage would be that suppliers of analytical chemicals, users with their own laboratories and independent laboratories will in general have to observe only one final date for selling or using the chemicals irrespective of the mercury compound and the area of use. It could also reduce the number of applications for dispensations made to KemI. Finally, monitoring would be facilitated at all levels.

Proposals

Mercury compounds for analyses, other than those specified above in the impact assessment, should be covered by a general ban.

KemI considers, however, that mercury compounds for use in analyses other than those specified above in the impact assessment should be granted a time-limited exemption from the ban and be allowed to be marketed until 31 December 2007 and used until 31 December 2008.

6.3 Disinfection of medical equipment

The preservative thiomersal, an organic mercury compound (merthiolat, CAS No 54-64-8) is used to disinfect certain medical equipment used, for example, in the case of transfusions and dialysis. This is sophisticated equipment which is used rarely and is only to be found in a few hospitals in the country, mainly university hospitals. The Clinic for Transfusion Medicine at the Karolinska University Hospital states that 29 g of thiomersal was used in 2003 in the case of transfusion equipment. For dialysis equipment a further 40 g was used.

6.3.1 Are there alternatives to mercury?

The manufacturers of the equipment approve only thiomersal as a disinfectant for various reasons. In some cases one manufacturer no longer guarantees the safety of the product if alternative disinfectants are used. Another manufacturer claims that no other preservative keeps the equipment disinfected for as long as necessary. Attempts have been made to replace thiomersal but this has not been successful since the manufacturers oppose it (Vass, personal communication). This also means a further cost for health care since the used thiomersal solutions are treated as hazardous waste.

6.3.2 What would be the impacts of a ban?

The health services could not guarantee patient safety when equipment is used where preservatives are needed because the manufacturer does not guarantee that the equipment will operate correctly.

6.3.3 Conclusions

There are currently no alternatives to thiomersal for disinfecting certain transfusion and dialysis equipment. In order to influence the manufacturers to develop alternatives a time-limited exemption is needed.

6.3.4 Proposal

Mercury compounds for disinfection of transfusion and dialysis equipment should be covered by a general national ban.

KemI considers, however, that thiomersal for disinfecting transfusion and dialysis equipment should be granted a time-limited exemption from the ban and be allowed to be marketed until 31 December 2007 and used until 31 December 2008.

6.4 Research and development

Research in the academic world and as part of commercial R&D efforts often leads to the development of new products. KemI considers that it is important that new applications of mercury and mercury compounds should not come into use and that new products containing mercury should not be put on the market. A general ban on the handling of mercury would counter such a new supply of mercury to society.

As part of research, various analyses of mercury and mercury compounds need to be carried out. The exemption proposed for the use of mercury compounds (see above,

Paras 6.2.2-6.2.7) should satisfy many of the needs of R&D. But mercury compounds have areas of use other than as analytical chemicals. Below are some examples that have emerged from our investigation:

Organic and inorganic mercury compounds are used as catalysts in synthetic organic chemistry, principally for research purposes. For example, mercury oxide or mercury acetate can be added in small amounts to make a chemical reaction go faster. Generally a synthesis route is followed which is published in the international literature and alternative routes are not practicable.

In certain research studies on membrane proteins mercuric chloride is used to inhibit transport through the membrane. Alternatives are available (e.g. cytochalasin, CAS No 14930-96-02).

In protein structure research using X-ray crystallography heavy metals are used to derivatise the proteins. Mercury, platinum and lead can all be used but mercury is used most. In Sweden this type of research is carried out by around 10 research groups in universities and research institutes and in research-oriented companies such as medicinal products companies. The Institute for Molecular Biology at the Swedish Agricultural University states that they annually use about 50 mg of mercury compounds for this purpose.

6.4.1 Are there alternatives to mercury?

In certain cases there may be alternatives to mercury and mercury compounds. According to our information alternatives are available, for example, for certain uses in membrane-protein research.

Time is needed to develop alternatives in those fields where there is currently no alternative to mercury compounds.

6.4.2 What would be the impacts of a ban?

A general ban on the use of mercury will counter the possibility that mercury and mercury compounds will find new applications in R&D activity, which will have a positive effect on the phasing out of mercury.

If a ban on the use of mercury in research is introduced in Sweden the impacts on academic values could be substantial. New research results could fail to be accepted if they are based on methods that are not scientifically well-based. This could have effects on what research could be carried out in Sweden in future. A possible impact is that doctoral candidates would be forced to go abroad to take their degree.

6.4.3 Conclusions

KemI considers that it is important that new applications of mercury and mercury compounds should not come into use and that new products containing mercury should not be put on the market. The use of mercury compounds in R&D should therefore in the long term be replaced where possible. To avoid drastic impacts on research that is currently in progress, a transitional period is required for the development of alternative methods. In KemI's judgement a period of three years from the date on which the ordinance and regulation come into force is a reasonable

transitional period. After that it will be possible to apply for an exemption if there are exceptional reasons to use mercury.

6.4.4 Proposal

Mercury compounds for use in R&D should be covered by a general national ban.

KemI considers, however, that mercury compounds for R&D in industry and universities should be granted a time-limited exemption from the ban and be allowed to be marketed until 31 December 2007 and used until 31 December 2008.

6.5 Chlor-alkali industry

In Proposition 1997/98: 145 the government took the view that the use of mercury in the chlor-alkali industry could continue until 2010. Sweden has also undertaken in international agreements (North Sea Conference and Oslo and Paris Conventions) that mercury-based methods used in the manufacture of chlorine and caustic soda will be phased out by 2010 [OSPAR decision 1990/3]. The Swedish Environmental Protection Agency (SEPA) previously identified a need for special legislation to phase out mercury-based methods in the chlor-alkali industry by 2010.

Through the IPPC Directive (Integrated Pollution Prevention and Control Directive, 96/61/EC) a BREF (Best Available Techniques, BAT, Reference Document) has been produced in which processes using mercury are not regarded as being the best available technique (BAT). A strict interpretation of the IPPC Directive implies that BAT will be introduced in October 2007. The licensing authorities in each Member State have to take account of the local circumstances and preconditions in their assessment of what the BAT is in each individual case. Therefore there will be a gradual phasing out of mercury cells in different Member States.

In Sweden there are two chlor-alkali plants that use mercury cells. Eka Chemicals AB in Bohus, owned by Akzo Nobel, has a factory dating from 1969 with a capacity of 100,000 tonnes of chlorine gas per annum. Hydro Polymers AB in Stenungsund, owned by Norsk Hydro, has a factory dating from 1969 with a capacity of 120,000 tonnes of chlorine gas per annum.

Hydro Polymers AB is going to phase out mercury cells by 2010 (minuted, *inter alia*, at a consultation meeting with the County Administrative Board on 8 June 1999). Eka Chemicals AB has stated that chlor-alkali production in Bohus will be discontinued before 2010 for market reasons [Eka Chemicals AB, 2004].

The total quantity of metallic mercury in use in the chlor-alkali industry in Sweden is about 400 tonnes. In 2002 the companies reported emissions to air of about 38 kg of mercury, to water about 1.6 kg, and residual amounts of about 3.4 kg in products. During the last few years the mercury supplied to the plants has come from recovered mercury (mainly from SAKAB) and from the companies' own stocks (Jorlöv and Andersson, personal communication).

6.5.1 Are there alternatives to mercury?

There are three different processes for chlor-alkali production. Two processes: the mercury method and the diaphragm technique date from the end of the 19th century while the third process: membrane technique was developed on an industrial scale in

the 1970s. Membrane cells release less hazardous substances and are more energy-efficient than the older techniques.

6.5.2 *What would be the impacts of a ban?*

Since mercury-based chlor-alkali production must be phased out in accordance with the IPPC Directive a national ban in accordance with previous international commitments will not involve any further major impacts.

6.5.3 *Conclusion*

A strict interpretation of the IPPC Directive implies that the best available method, i.e. the membrane technique, must be introduced in October 2007. Since 1990 the companies affected have been aware of Sweden's commitment to phase out the mercury method by 2010. Thus, there have been good opportunities for these companies to plan and carry out a switch to alternative production techniques.

Both plants are 35 years old and use outmoded technology. If the companies intend to continue with chlor-alkali production a change of process would probably take place for economic reasons before too long, irrespective of the legal requirements.

A national ban on the use of mercury in the chlor-alkali industry from 2010 will produce no greater further impacts for the companies affected beyond those which follow from the IPPC Directive. KemI sees good reasons to adhere to the date of 2010 laid down by the government to ensure an end to the use of mercury in the chlor-alkali industry.

6.5.4 *Proposal*

The use of mercury in the chlor-alkali industry should be covered by a general national ban.

KemI considers, however, that mercury for chlor-alkali production should be granted a time-limited exemption from the ban and be allowed to be marketed and used until 31 December 2009.

6.6 *Cosmetics*

6.6.1 *Are there alternatives to mercury?*

According to the Cosmetics Directive it is not permitted to place cosmetic products on the market if they contain mercury or mercury compounds. The Directive, however, contains exemptions that mean that phenylmercury salts and thiomersal are permitted in eye make-up and products for removing eye make-up subject to maximum mercury content of 0.007%.

Phenylmercury salts and thiomersal are added as preservatives in eye products to minimise the risk of microbiological contamination and the spread of eye infections. There are, however, many other acceptable preservatives, e.g. methyl paraben and propyl paraben, which are used in eye make-up and products for removing make-up. In the judgement of the Medical Products Agency (MPA) there is no eye make-up or

product for removing make-up on the Swedish market which contains mercury (Guzikowski, personal communication).

6.6.2 *What would be the impacts of a ban?*

A ban on the use of mercury compounds in cosmetics would presumably not create any economic or practical impacts for industry since the available alternatives are already in use.

The consumers and the environment should not be affected either to any significant extent since the eye make-up and products for removing eye make-up which are on the Swedish market are already free from mercury.

6.6.3 *Conclusion*

There is no need to use mercury compounds in cosmetics since there are acceptable alternatives, which are considerably less harmful from environmental and health points of view. Using mercury in cosmetics means that mercury is spread via waste water to the sewage treatment plant and also into the solid-waste stream when packaging containing cosmetics residues is discarded. Even if the concentration is low this use contributes to an unnecessary spread of mercury.

6.6.4 *Proposal*

Mercury compounds in cosmetics should be covered by a general national ban.

6.7 *Equipment*

Equipment for various purposes can incorporate mercury-containing instruments such as thermometers and barometers, and electrical components such as relays, conductors, switches and circuit-breakers. These utilize mercury's special properties such as its high electrical conductivity, liquid state at room temperature, high density, and no problems with oxidation of the surface since it disappears rapidly when new mercury is dripped on it. Furthermore liquid mercury does not wet normally absorbent material such as paper.

Under current legislation it is forbidden to manufacture or sell mercury-containing measuring instruments and certain electrical components (see Annex 1 and 2). These goods may be imported from other EU countries but not from countries outside the EU. On the other hand this ban does not apply to equipment that contains such substances. In practice it has been possible to replace the instruments and electrical components concerned in most cases.

It is difficult to judge the effects of a general ban since it covers all goods, i.e. not just the instruments but also the equipment that contain the instruments. Currently such equipment can be imported from other EU countries and third countries.

Swedish suppliers of equipment are therefore treated unfairly compared with foreign suppliers. A general ban would mean that equipment that contains mercury could not be manufactured, sold, or imported from other EU countries and third countries. This means that Swedish industry could compete on equal terms with the foreign equipment suppliers.

It is not uncommon that incomplete information is provided about the composition of goods imported from other countries. The importer is then unaware that the goods contain mercury. Even if the goods are stated to contain mercury it can be difficult to identify the amount, which makes it difficult to check whether the ban is being observed. Despite these problems a ban on mercury is important since it gives a clear signal that the substance is undesirable and a general ban will presumably force the pace of development of alternative techniques.

Directive 2002/95/EC restricts the use of mercury and other hazardous substances in electrical and electronic equipment. The equipment covered by the Directive is regulated at EU level and not via national regulations. Lighting equipment is an example of an area regulated in the Directive. Information about the Directive can be found in the Legal Analysis (Annex 4).

Large quantities of mercury are stored in various types of instruments in society. New supplies of the substance occur in those areas which are not currently regulated, e.g. via new equipment. As regards equipment, the largest use probably takes place in professional use. Mercury in such equipment is presumably most often dealt with legally in the waste stream but there is still a risk of the substance spreading in the working environment and to the natural environment during manufacture and via the waste stream.

The basis of the equipment investigation consists of the report from the consultant study, which was carried out within the framework of the commission (Östman, 2004), the questionnaire responses submitted to KemI, and oral information from industry representatives. It emerges from these sources that the use of mercury in instruments has in many cases been replaced by other techniques. Below follows a description of the instruments that are banned and equipment that contains them.

6.7.1 Thermometers

Are there alternatives to mercury?

Mercury-containing thermometers have been banned since 1991 and only a few applications for exemptions for specific applications have been submitted since then. Sales have gradually decreased and were very low in 2003. Generally speaking there are currently no obstacles to measuring temperatures using other techniques.

A large number of mercury thermometers are fitted in autoclaves, and warming cabinets used in laboratories and in health care. When the thermometers have been broken or no longer register correctly, the equipment has been modified to allow the installation of, for example, a thermocouple, or the thermometer has been replaced with a more modern digital temperature-measuring device. These two techniques offer certain advantages as regards automation and the collection/recording of data. There are probably still several thousand mercury thermometers in autoclaves, and warming cabinets, which will be replaced as they become unserviceable.

In universities and colleges there are a few hundred pieces of equipment which are used to determine density and melting/boiling points. This equipment can be used until the mercury thermometers are no longer serviceable. Then they must be rebuilt or replaced.

One specific use of thermometers is in flash-point determination. This type of measurement is used in the oil industry and by companies providing analytical services. Flash-point measurement is regulated by Directive 67/548/EEC, which indirectly requires mercury thermometers be used (see discussion Chapter 5). Therefore these thermometers have an exemption from the current ban.

What would be the impacts of a ban?

Changing the temperature-measuring technique or replacing the equipment can initially have financial impacts on the organisations concerned. The capital costs of new, more modern equipment are often higher than for traditional equipment. This is not because the instrument in the equipment is mercury-free but because the equipment in its totality is more sophisticated, which for some users means that it is more efficient but for others it is more sophisticated than is needed for their particular application.

Flash-point determination is regulated by Directive 67/548/EEC, as mentioned before. According to the Directive the use of a special mercury-containing thermometer is an indirect requirement. The exemption for this thermometer expired on 31 December 2003 and therefore needs to be renewed.

Conclusion

Alternative techniques exist for most measurements and it seems as though thermometers in equipment have gradually been replaced by new techniques. A general ban therefore seems unlikely to produce any drastic consequences except possibly for smaller organisations providing analytical services for which it is not financially worthwhile to exchange old equipment for equipment which is now mercury-free. The equipment used for flash-point determination has a mercury thermometer which is designed for this purpose. The exemption for thermometers for flash-point determination in accordance with Directive 67/548/EEC expired on 31 December 2003 and it ought to be renewed, since the use of mercury-containing thermometers is controlled by the Directive.

Proposal

Equipment which contains mercury should be covered by a general national ban.

KemI considers, however, that mercury-containing equipment for flash-point determination in accordance with Directive 67/548/EEC should be granted a time-limited exemption from the ban and be allowed to be marketed until 31 December 2010.

6.7.2 Relays

Are there alternatives to mercury?

In relays a powerful electric current is turned on or off by the action of a less-powerful one. Small relays are found in printed circuit cards. Larger relays are to be found in, for example, stairwell lighting, signal systems, machinery and elevator controls, and traffic lights. Relays are a large group of products which have gradually been replaced by other electronics. The driving forces for this have been

developments in the electronics sector, increased pressure to phase out mercury, and increased awareness of the latent waste-situation.

What would be the impacts of a ban?

It appears that equipment consisting of mercury-containing relays is currently being replaced by alternative technology, and in the case of Banverket, Vattenfall, Svensk Energi and Svenska Kraftnät (see glossary for explanations), no mercury-containing components or equipment is installed when the old items are scrapped. Based on this information KemI judges that a ban will have no effects on this type of equipment.

Conclusion

A ban on equipment that contains mercury relays would probably have small, if any, impacts since there currently seem to be alternative techniques.

Proposal

Equipment using mercury-containing relays should be covered by a general national ban.

6.7.3 *Electrical conductors, switches and circuit breakers*

Are there alternatives to mercury?

Mercury-containing conductors, switches and circuit breakers use mercury in liquid form. The making or breaking of the electrical circuit is achieved in these cases by a mechanical action. The technique is old and has been used in thermostats, tilting switches, gas-operated relays and pressure switches, in which a change in position makes or breaks an electrical circuit. Common applications have been as level regulators for pumps and tanks. The function could also be to close a circuit when a cover is opened, for example the lid of a car boot. In the majority of applications there are established alternative techniques and practically no exemptions have been applied for since 1998.

There is an exemption until 31 December 2005 for electrical switches as spare parts for *personal motion alarms* which emit a radio signal indicating that the person is immobile if no change in position takes place within a certain period. These alarms are used in certain types of employment such as driving underground trains.

According to information from Nordic Alarm AB an alarm of this type which does not use mercury and which has been tested with good results will come on the market in 2004 (Johnsson, personal communication). It has not been possible to quantify imports of these alarms as part of our commission. KemI judges, however, that only a few companies are involved.

For *tracking devices for wildlife* there are still no satisfactory alternatives, according to Scan Craft Data AB (Boxström, personal communication), and therefore Swedish companies have sought and been granted dispensations to manufacture and sell them. An alternative where the mercury has been replaced by a gold-plated ball has been tested but with poor results. The ball gets stuck in the device because of mechanical jolts and corrosion by the humid environment, and has therefore given false signals. Mercury-containing transmitters are moreover smaller and lighter than others and can therefore be used for migratory birds.

Mercury is used in ignitrons or mercury-arc rectifiers whose function is to convert alternating electric current to direct current. There are alternative technologies.

What would be the impacts of a ban?

For conductors, switches and circuit breakers there are in most cases alternative technologies, and very few applications for exemptions have been submitted since 1998. No drastic impacts are therefore expected from a general ban.

Current personal motion alarms contain electrical switches using mercury. A mercury-free version will become available in the near future according to oral information from a Swedish manufacturer. Assuming the new alternative functions well, KemI's judgement is that a general ban will not mean adverse impacts such as increased risks for the categories of people who use these alarms.

It appears however that there are still no workable alternatives in the case of tracking devices for wildlife despite efforts to develop such. A general ban would make it impossible to carry out research where tracking devices are needed.

Conclusion

For most of the uses there are alternative techniques. An exemption from a general ban is however required for tracking devices for use in wildlife research. KemI expects that efforts will continue to be made to find alternative techniques.

Proposal

Equipment comprising electrical conductors, switches and circuit breakers which contain mercury should be covered by a general ban.

KemI considers, however, that tracking devices for use in wildlife research should be granted a time-limited exemption from the ban and be allowed to be marketed until 31 December 2008.

6.7.4 Continuous current transfer

Are there alternatives to mercury?

In many situations the transfer of electrical current from a shaft to a rotating part takes place using mercury, e.g. in *contactors* for cranes and packaging machines. After the review within the government commission 1998 the American manufacturer developed alternative techniques but Swedish customers prefer the mercury technique. The alternative technique seems, however, to be good enough to be able to replace the use of mercury.

Ventilation ducting and cans are manufactured using *seam-welding machines*. The technique used is a special application of current transfer. A wheel conducts an electric current through the material at the same time as a welding rod is fed in. The wheel rolls along the material and the current is transferred from the shaft to the circumference of the wheel since it is filled with mercury. Two manufacturers, in Italy and Switzerland, dominate the world market. Just below half the machines are of Italian manufacture. The technique is slightly different for straight and curved seams. The Swiss manufacturer has developed a mercury-free technique for straight seams but the corresponding development for curved seams has proved difficult.

The Italian manufacturer has not regarded the Swedish market as sufficiently interesting to consider investing in development.

There are about 100 seam-welding machines in Sweden (Hörnfeldt, personal communication). The mercury in the wheel oxidises and is replaced after 2-5 years. The quantity in the wheel is on average about 60 g so the total quantity in all the machines is probably about 10 kg. The turnover of mercury is of the order of 5 kg per annum.

More than half the products manufactured using seam welding are exported.

Seam-welding machines have a life of at least 30 years so replacement of the existing machines will take many years. It is possible to rebuild the Swiss straight-seam machines but for machines for welding curved seams, which make up about half the total, there is currently no alternative technique. It is therefore unreasonable to expect that a mercury-free technique will be available within a few years.

What would be the impacts of a ban?

For *contactors* in general it appears that adequately good alternatives are available and therefore a general ban would not mean drastic impacts on suppliers or users.

The situation is different for *seam-welding machines*. A new Swiss seam-welding machine for straight seams, with the possibility of employing an alternative technique, costs almost SEK 2 million (217,704 EURO) while modifying an older machine costs about SEK 100,000 (10,885 EURO). Only small and medium-sized enterprises manufacture ventilation ducting, and buying alternative equipment is almost unthinkable. A gradual rebuilding of the Swiss machines is a possibility for moving away from the use of mercury in the case of straight seams. Of the Swiss seam-welding machines, which make up 60% of the total, over half have been rebuilt to be mercury-free, according to the Association of Swedish Engineering Industries (VI)

For manufacturers of ventilation equipment and cans a ban would mean that existing equipment would need to be replaced or modified if that has not already been done. The ASEI states that a possible impact of a national ban would be that the manufacture of ventilation equipment moves abroad, costing 700 jobs. The ventilation systems would then be imported.

Conclusion

Over half the Swiss seam-welding machines have already been modified and KemI expects more to be modified. For straight seams it thus seems that the trend is in the desired direction. But several more years will probably be needed to modify all the existing machines.

Curved-seam machines are a greater problem since no alternative technique has yet been found. More time is needed for development here and KemI expects that efforts will be made to find alternatives in this case as well.

It is therefore currently necessary to grant exemptions for seam-welding machines, but for different periods for the two types because the development of alternative techniques is at different stages. The exemption would mean that there would be no change as regards the manufacture of ventilation systems and the number of jobs.

The exemption should have the same duration as was proposed by KemI in 1999: straight-seam welding until 31 December 2010 and curved-seam welding until 31 December 2014. The proposal was regarded positively by the industry in 1999. KemI assumes that efforts will be made to find alternative techniques for both types of seam.

Proposal

Equipment containing mercury for continuous current transfer should be covered by a general national ban.

KemI considers, however, that seam-welding wheels as spare parts and metallic mercury for refilling them should be granted a time-limited exemption from the ban and should be allowed to be marketed for the welding of straight seams until 31 December 2010 and for the welding of curved seams until 31 December 2014.

6.7.5 Barometers and manometers

Are there alternatives to mercury?

In barometers and manometers a mercury column provides a counter to a pressure, so that the height of the column indicates the pressure measured. This technique has been used for, and other applications, measuring atmospheric pressure, blood pressure and differential pressure. In measuring differential pressure, a restriction in a flow of water or gas is registered and from this the size of the flow can be calculated. Mercury columns can be used for pressure and flow measurements both in the domestic and service sectors and in industry and the public sector. A mercury column can be connected directly to a pointer or to a pen recorder to transmit pressure, temperature, levels in tanks, etc. The column can also be coupled mechanically to a control unit that controls levels within a set range. In most cases there are alternatives to barometers and manometers in the form of electronic techniques and very few dispensations have been given since 1998.

A special form of pressure measurement occurs in industry in the case of polyethylene manufacture where a *precision measurement* is made at high temperature. The polyethylene product is evaluated by the pressure measurement, which is therefore a quality-assurance parameter. Alternatives have been tested over many years but none of them has given the required result.

What would be the impacts of a ban?

In this area of application mercury-based equipment has already been replaced to a large extent. This means that the financial impacts on the companies affected should be marginal.

Special types of pressure measurement, such as precision measurement, would however be made impossible by a general ban. The only alternative would be to send samples of polyethylene products abroad to have them evaluated, which would mean a delay to production.

Conclusion

It would be possible to extend the current ban without significant impacts since there are alternative techniques in most cases. For special pressure-measurement: in

polyethylene manufacture, where alternative techniques are still lacking there will be an opportunity for companies affected to apply for an exemption if the ban would create drastic impacts.

Proposal

Barometers and manometers that contain mercury should be covered by a general national ban.

6.7.6 Gyroscopes

Are there alternatives to mercury?

Gyroscopes, used for example for navigating small craft, appear to have been replaced by GPS (Global Positioning System). Navigation by GPS makes use of satellites.

What would be the impacts of a ban?

Based on information from the Swedish Armed Forces and a supplier of navigational instruments to the Armed Forces KemI judges that a ban would not have any impacts on manufacturers, suppliers or users.

Conclusion

Since modern techniques are available mercury-containing gyroscopes are not needed.

Proposal

Gyroscopes which contain mercury should be covered by a general national ban.

6.8 Summary of proposals for exemptions

In the impact assessments KemI has identified that analysis of mercury ought to be exempted from the ban with no time limit.

The following uses are judged to be in need of time-limited exemptions from a general national ban on mercury:

- amalgam in hospital dental care (adult patients)
- COD analyses
- analyses in accordance with international standard methods in the medicinal products sector
- analysis and R&D in medical diagnostics
- other analyses not specified above
- disinfection of some medical equipment
- R&D in industry and universities
- chlor-alkali production
- tracking devices for wildlife
- seam welding
- thermometers for flash-point determination

For other areas of application KemI has not identified any need for exemptions and they should be covered by the general ban when it comes into force.

7 PROPOSED ORDINANCE AND REGULATIONS

7.1 Content of proposal

The proposal has been formulated as a general ban which means that mercury and goods containing mercury may not be placed on the market in Sweden or commercially exported from Sweden. Mercury must not be used either. The proposal is introduced by a definition of what is regarded as mercury. From the definition and from the bans it is clear that it is only the use of mercury which is prohibited. The use of goods containing mercury is thus permitted. This means that mercury contained in goods which have been placed on the market in Sweden before the ordinance comes into force can continue to be used. According to the existing ban it is forbidden to manufacture or sell certain types of goods that contain mercury and to use these if they were not in use before 1 January 1995, and also to export mercury from Sweden. The proposed ban is structured in a different way and applies to the person who first makes a mercury-containing good available on the Swedish market. Other persons are thus not affected by the ban: that is unnecessary since the proposal means that the banned goods are never placed on the market in Sweden. If a banned good should despite the ban be placed on the market and found in the hands of a person other than the one who placed it on the Swedish market, the former cannot be held responsible for the situation. That does not mean, however, that the good *per se* is permitted. It should therefore, according to the Swedish Environmental Code, be possible to confiscate the product from re-sellers and retailers and others who are not affected directly by the ban.

The use of mercury and goods containing mercury is regulated under EC law, in a large number of directives and EC regulations. Some of these are fully harmonised, which means that it is very difficult for Sweden to introduce a national ban on mercury. It has therefore been regarded as necessary to make exceptions for them in the Swedish mercury ban. We have chosen to indicate these exceptions by listing the various areas of use that are regulated in the current directives and EC regulations, as well as the Swedish regulations that implement the directives. The uses of mercury which are regulated in other directives and EC regulations, and which are not named in our draft regulation are thus not covered by the exceptions from the ban, and are thus banned.

The proposed exceptions in Items 4-5 in Section 10b cover all the vehicles that are covered by Directive 70/156/EEC on the type approval of motor vehicles and trailers for these vehicles, and Directive 2000/53/EC on end-of-life vehicles. If these Directives are broadened these vehicles too will thus be covered by the exceptions in the Swedish regulation.

The formulation of the exceptions means that it will be easier for the reader to understand what is not covered by the Swedish ban on mercury, which is good for reducing legal uncertainty.

7.1.1 Authority to grant exemptions and dispensations

The legislative proposals also include giving authority to KemI to issue exemptions from the bans. To increase predictability the draft ordinance specifies a number of

criteria which must be satisfied in order for KemI to grant an exemption. The first three criteria concern the interest served by the use, available alternatives and human and environmental exposure. These must all be satisfied for an exemption to be granted. There is however also a possibility of granting an exemption if there are other special reasons. In this investigation the need for a number of exemptions has been identified in the impact assessments (Chapter 6). Assuming that the proposed regulatory scheme comes into force, KemI intends to amend its regulation in accordance with what has emerged in this investigation. A proposed amendment to the regulation, including the suggested exemptions, is presented below (see Para 7.3).

KemI judges that the power to grant dispensations in individual cases has been an important part of the success with and acceptance of the current rules. It should therefore remain within the framework of a general ban. It is therefore proposed that KemI should continue to have the possibility of granting dispensations in individual cases if there are exceptional reasons.

Since the proposed ban affects areas which are regulated in EC law for health and safety reasons, and EC rules have been incorporated into Swedish law²⁷, *inter alia* via regulations issued by public authorities, it is possible that these regulations will need to be amended. It is therefore important that the powers delegated to the public bodies concerned are, if necessary, amended so that it is possible to adapt regulations previously formulated in accordance with EC law to a Swedish ban on mercury, which is justified for environmental reasons.

7.1.2 Naturally occurring mercury

Mercury occurs naturally: in coal, ore and ore concentrate, for example (see further below). These products have been expressly exempted from the ban since the impacts of a ban have not been investigated in detail as part of this commission.

Ore can be upgraded to ore concentrate, also called dressed ore. Ore concentrate is used for the production of metals and metal alloys. For zinc production the ore is concentrated to 50-65% pure zinc (Borell, personal communication). The mercury content of ore and ore concentrate varies between 0.1 ppm (parts per million) and 1000 ppm, depending on the level in the crude ore. Since ore concentrate contains the metals in concentrated form it presumably contains higher concentration of mercury than the untreated ore, but with the same order of magnitude.

In 2003 dressed zinc ore from Boliden's mines contained 144 g of mercury per tonne, and dressed copper ore contained 69 g of mercury per tonne (Hylander, personal communication). Statistics from Statistics Sweden (SCB) show that 305,057 tonnes of zinc ore were exported from Sweden in 2003, though in practice it is actually ore concentrate that is exported (Borell, personal communication). The zinc concentrate exported contained an estimated total of about 40 tonnes of mercury. In the same year exports of copper concentrate were 125 tonnes, corresponding to about 9 kg of mercury.

²⁷ For example, the Toy Safety Directive and the Cosmetics Directive contain limits on how much mercury toys may emit and how much mercury cosmetics may contain respectively.

In smelting works mercury is removed in the ore-dressing processes to prevent large discharges and to stop mercury becoming an unacceptable constituent of the smelted products (Boliden, 2004). There is nothing to prevent the mercury recovered in smelting works in another country being sold on the global market. This is unfortunate in relation to the Swedish export ban on mercury, which has been introduced to prevent Sweden contributing to the global trade in mercury.

KemI considers that there are strong objective reasons to supplement the proposed bans with export restrictions which also cover the mercury contained in raw materials such as ore and ore concentrate. For example, a responsibility could be introduced, which would mean that mercury obtained as a by-product from Swedish ore and ore concentrate must be returned for final disposal in Sweden. In view of the interpretations and scope which KemI has applied to the commission, the impacts of regulating exports of ore concentrate have not been investigated, and KemI is therefore not putting forward any proposals to address that issue now. It is important that a separate investigation of this be carried out.

7.1.3 Export of waste

The aim of the current rule: that mercury may not be commercially exported from Sweden is primarily to prevent the export of mercury-containing waste. However, KemI's regulations contain a general exemption for the export of mercury-containing waste if the Swedish Environmental Protection Agency (SEPA) grants consent for its transport in accordance with the provisions on the export of waste. This rule was introduced in accordance with Sweden's intention that mercury-containing waste must be processed for final disposal and not recovered.

The proposals contain an explicit ban on the export of waste containing mercury. To make this clear the ban on the export of waste is contained in a separate paragraph. This is also a practical solution since the exemptions from the ban would otherwise apply also to waste, which is not the intention.

For uses where mercury is still permitted there can, however, be reasons to permit some recovery of substances and materials. The general exemption to KemI's regulation of the export of mercury-containing waste has therefore been replaced by the provision that in individual cases SEPA can grant a dispensation for the export of waste for recovery, if there are special reasons. SEPA has also been given the possibility of specifying that the mercury shall be returned to Sweden for final disposal.

There may be a need to state a limit for the level of mercury in waste similar to the rules for the final disposal of mercury-containing waste, but an investigation of this has not been possible within the time frame of the commission.

7.1.4 Export and re-import for repair, etc.

Since the proposal means that goods, which have already been put on the market in Sweden, can continue to be used it is proposed that it will also continue to be possible to export mercury-containing goods for repair and calibration and to re-import them. It is however proposed that this provision be moved from KemI's regulation to the ordinance. The principal reason for this is that the exemptions granted by KemI will consist solely of time-limited exemptions that affect uses

where there is no existing available alternative and there are other special reasons. To put this type of provision in the ordinance, rather than in KemI's regulations, is in better agreement with the criteria laid down for when exemptions may be granted by KemI.

7.2 Draft of an ordinance (2004:X) amending Ordinance (1998:944) concerning prohibitions etc. in certain cases in connection with the handling, import and export of chemical products

Section 8 By mercury is meant mercury and chemical compounds and preparations containing mercury.

Section 9a Mercury may not be placed on the market in Sweden, used, or commercially exported from Sweden.

Section 9b Goods that contain mercury may not be placed on the market in Sweden, or commercially exported from Sweden.

Section 9c Waste that contains mercury may not be exported from Sweden.

Section 10a The prohibitions in Sections 9a-b do not apply to mercury which occurs naturally in coal, ores and ore concentrates²⁸.

Section 10b The prohibitions in Sections 9a-b shall not apply to the following uses

1. Electrical and electronic products covered by Section 1a of this ordinance²⁹,
2. Batteries covered by Section 3 of Ordinance (1997:645) concerning batteries,
3. Packaging and packaging components, which are covered by Sections 12 and 14 of this ordinance,
4. Motor vehicles and trailers for these vehicles, which are covered by the type-approval rules in the Vehicle Ordinance (2002:925),
5. Light trucks and passenger cars other than EC-type-approved passenger cars, which are covered by Section 2 of the Ordinance (2003:208) concerning bans on certain metals in cars,
6. Medical devices for in-vitro diagnostics, which are covered by the Act (1993:584) on medical devices and
7. Human medicinal products and veterinary medicinal products, which are covered by the Medicinal Products Act (1992:859), and by Council Regulation 2309/93/EEC laying down Community procedures for the

²⁸ See discussion in Para 7.1.2.

²⁹ Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment has still not been implemented in Swedish legislation. The exemptions arise from annexes to the Directive. The Member States must bring into force the laws and other enactments necessary to implement the Directive by 13 August 2004.

authorization and supervision of medicinal products for human and veterinary use, and establishing a European Agency for the Evaluation of Medicinal Products³⁰.

Section 10c The prohibition in Section 9b does not apply to the commercial export and re-import of goods for repair or calibration abroad.

Section 11 The Swedish Chemicals Inspectorate may issue regulations concerning further exemptions from the prohibitions in Sections 9a-b if

1. the use satisfies an essential need, and
2. no other alternative is available on the market, and
3. the use does not involve any pronounced contribution to the exposure of Man or the environment, or
4. there are other special reasons.

If in an individual case there are exceptional reasons, the Swedish Chemicals Inspectorate may grant dispensations from the prohibitions in Sections 9a-b.

In individual cases, and if there are special reasons, the Swedish Environmental Protection Agency may grant dispensations as regards the export of waste containing mercury for recovery. The Swedish Environmental Protection Agency may impose the condition that the mercury shall be returned to Sweden for final disposal.

7.3 Changes in 'the Swedish Chemical Inspectorate's regulations

The draft ordinance contains an authority for the Swedish Chemicals Inspectorate to grant exemptions from the prohibitions in the ordinance (Section 11). Assuming that the proposed ordinance comes into force, the Swedish Chemicals Inspectorate intends to amend its regulation as below.

Section X. Despite the prohibitions in Section 9 a-b of Ordinance (1998:944) concerning prohibitions etc. in certain cases in connection with the handling, import and export of chemical products, mercury and goods which contain mercury may be placed on the market in Sweden and used in accordance with what is stated in Annex X.

Section X. Anyone who commercially imports into Sweden, manufactures, sells or uses mercury or goods which contain mercury, and are listed in Annex X, shall record

1. the date of importation, manufacture or sale

³⁰ As regards human medicinal products [2001/83/EC] further assessment about possibilities for introducing a national ban on mercury might be motivated, see further the discussion in Annex 4.

2. the date of use of mercury
3. the number of units
4. the quantities of mercury
5. the intended area of use
6. if the units have been sold, the purchaser's name and address, or if not sold what has happened to them.

In addition to what is stated in the first paragraph, when dental amalgam is used the dentist performing the treatment shall record the reasons why other relevant treatment methods could not be used.

The obligation to keep records about goods that contain mercury applies only if the goods are placed on the market after these regulations come into force.

Section X. The information shall be entered in a special register or kept in some other way so that it can easily be checked.

Section X. The one responsible for keeping records shall save the information for so long as he is carrying out any activity where record-keeping is required and for a further three years thereafter.

Section X. Information recorded in accordance with section X shall be handed over to the Swedish Chemicals Inspectorate on request.

Annex X

In this Annex existing exemptions are indicated by *italics*. The dates for the new exemptions are based on the assumption that they come into force on 1 July 2005. Mercury and mercury compounds and preparations containing mercury as well as goods that contain mercury

	May be placed on the market in Sweden until	May be used for the indicated use until	May be placed on the market in Sweden as a spare part for the indicated use until
Relays, electrical contacts			
1. <i>Relays with mercury wetted contacts with not more than</i>			
<i>a. 1.5 g of mercury per contact</i>	-	-	31 Dec. 2004
<i>b. 0.05 g of mercury per contact</i>	-	-	31 Dec. 2007
2. <i>Relays with mercury wetted contacts with not more than 1.5 g of mercury per contact and intended for professional installation</i>	-	-	31 Dec. 2007

	May be placed on the market in Sweden until	May be used for the indicated use until	May be placed on the market in Sweden as a spare part for the indicated use until
3. <i>Electrical contact breakers for indication position, for professional assembly in personal alarm systems.</i>	-	-	31 Dec. 2005
4. <i>Electrical contacts for ABS brakes, for professional assembly in motor vehicles</i>	-	-	31 Dec. 2006
5. <i>Electrical contact breakers for airbags, for professional assembly in motor vehicles</i>	-	-	31 Dec. 2006
Measuring instruments			
6. <i>Manometers for cell counting instruments for hospital laboratories</i>	-	-	31 Dec. 2007
7. <i>IR instruments for professional measuring of thermal radiation. IR detectors for such instruments.</i>	-	-	31 Dec. 2007
8. <i>Polarographs for professional measuring. Electrodes for such instruments.</i>	-	-	31 Dec. 2007
9. Thermometers for flash-point determination as provided in Directive 67/548/EEC	31 Dec. 2010	-	-
Analytical chemicals			
10. Mercury compounds for the analysis of mercury	until further notice	until further notice	-
11. Mercury compounds for analyses in accordance with international standard methods in the medicinal products sector	31 Dec. 2011	31 Dec. 2012	-

	May be placed on the market in Sweden until	May be used for the indicated use until	May be placed on the market in Sweden as a spare part for the indicated use until
12. Mercury compounds for the analysis of COD and in vials for COD analysis	31 Dec. 2007	31 Dec. 2008	-
13. Mercury compounds for analysis and research and development in medical diagnostics	31 Dec. 2007	31 Dec. 2008	-
14. Mercury compounds for analyses, other than as in 10-13 above	31 Dec. 2007	31 Dec. 2008	-
Research and development			
15. Mercury compounds for research and development in industry and universities	31 Dec. 2007	31 Dec. 2008	-
Disinfection of medical equipment			
16. Thiomersal for disinfection of transfusion and dialysis equipment	31 Dec. 2007	31 Dec. 2008	-
Chlor-alkali production			
17. Mercury for chlor-alkali production	31 Dec. 2009	31 Dec. 2009	-
Seam welding			
18. Seam-welding wheels and metallic mercury for refilling these for the welding of			
- straight seams	-	-	31 Dec. 2010
- curved seams	-	-	31 Dec. 2014
Tracking devices			
19. Tracking devices for wildlife research	31 Dec. 2008	-	-

	May be placed on the market in Sweden until	May be used for the indicated use until	May be placed on the market in Sweden as a spare part for the indicated use until
Dental amalgam			
20. Dental amalgam for use in hospital dental care	31 Dec. 2008	-	-
21. Dental amalgam for use on adult patients in hospital dental care when, for special medical reasons, other treatment methods cannot be used with satisfactory results after evaluation of the individual case. Treatment may only take place in dental clinics.	-	31 Dec. 2008	-

8 IMPACTS ON SMALL ENTERPRISES

This chapter analyses the impacts which can be expected to arise for small enterprises, both from the proposed ordinance and from the changes which KemI intends to make in its regulation, assuming that the ordinance comes into force. In what follows, both the ordinance and the amendments to the regulation are referred to as "the proposal".

8.1 Introduction

According to Ordinance 1998:1820 on the special impacts analysis of the effects of regulation for the circumstances of small enterprises (the SimpLex Ordinance), the impacts analysis must consider working conditions, competitiveness, and other conditions.

The size of an enterprise is often assessed on the basis of the number of employees. In Sweden enterprises with up to 49 employees are defined as small enterprises, while ones with 50-1999 employees are reckoned to be medium-sized. Above this figure enterprises are defined as large. The analysis deals with impacts, in addition to those already mentioned in the impact assessment, which can particularly affect small enterprises with up to 49 employees. Other criteria can be used to categorize small enterprises, such as turnover and business activity, but for reasons of time it has not been possible to do more than take account of them in very broad terms. If the enterprise has fewer than 50 employees but is part of a larger concern or group of companies it has not been taken to be a small enterprise.

The analysis is based on the description of the problems that have already been presented in this report, and starts from the draft proposal and the exemptions included in the suggested regulation. The need for information is touched on in Chapter 9 Conclusions and discussion. Information on the interested parties consulted and how this work was carried out is described in Chapter 1.

8.1.1 Scope of the SimpLex analysis

The two companies active in chlor-alkali production in Sweden are characterized as large enterprises, from the number of employees, type of ownership and capital intensity. The impacts on these two companies will therefore not be analysed further in this part of the report.

For the handling of mercury for disinfecting medical equipment, a time-limited exemption is proposed which takes account of the time needed to develop alternatives to thiomersal for the disinfection of transfusion and dialysis equipment. To the best of KemI's knowledge there are currently no manufacturers in Sweden of thiomersal or other mercury compounds for disinfecting medical equipment, though a number of suppliers of thiomersal are established in Sweden. Its use occurs only in hospitals, which are not regarded as falling within the definition of small enterprise. This use of mercury will therefore not be analysed in this chapter.

Other limitations on the SimpLex analysis relate to the uses of mercury in the cosmetics industry. In the impact assessments it has been found that a ban on the use

of mercury compounds in cosmetics would probably have no financial or practical impacts on the economy, since the industry already uses other available alternatives.

Equipment other than seam-welding machines will not be dealt with in this analysis since in KemI's judgement there are no small enterprises that are affected by a ban. Currently, very few applications for dispensations are being submitted as regards instruments covered by the existing regulations, indicating that a switch to available alternatives has already largely occurred.

For more information on the use of mercury in chlor-alkali production, cosmetics, the disinfection of medical equipment and other equipment, see the impact assessments in Chapter 6.

8.2 Legal changes in the draft proposal which affect small enterprises

In the impact assessments, three areas of use have been identified for which an analysis of the impacts on small enterprises is justified: dental amalgam, analytical chemicals and reagents, and seam welding.

8.2.1 Amalgam

The handling of mercury in the form of amalgam has not been regulated before but the use has been substantially reduced because of, among other things, the agreement on phasing out amalgam in dentistry for children and young people. Since amalgam has not previously been covered by any national regulatory scheme, this can mean impacts on manufacturers and suppliers of tooth-filling materials, many of which are small enterprises.

8.2.2 Analytical chemicals and reagents

Use of mercury compounds as analytical chemicals and reagents has not been regulated previously. For the following uses of mercury compounds in analysis various time-limited exemptions are proposed: for use according to international standard methods relating to medicinal products; analysis of COD, including vials for COD analysis; analysis, research and development in the field of medical diagnostics; and other categories of analysis. An exemption for mercury compounds for the analysis of mercury is proposed with no time limit.

8.2.3 Seam welding

Welding wheels in seam-welding machines have previously been a non-regulated area. In accordance with the proposal, companies that use such equipment will be granted an exemption with a fixed final date for such handling of mercury. A distinction is made in the proposal, depending on whether the welding is of straight or curved seams. The proposal is in agreement with the notification, submitted to the Commission in 2000, which did not encounter any resistance at that time (see Para 2.2). In the impact assessment it has emerged that many of the seam-welding companies are small enterprises, which could be affected by the proposal.

8.3 Identification of the number of small enterprises in the industries affected

The number of small enterprises affected in each industry, based on their size, i.e. principally on the number of employees, is identified below.

8.3.1 Amalgam

There are two manufacturers and six distributors of dental amalgam in Sweden. Of the six distributors four are small enterprises. The two others are parts of larger concerns, and are thus not dealt with in this analysis. Of the four small enterprises two distribute dental filling materials from a foreign manufacturer. One of the manufacturing companies is a small enterprise, while the other is part of a larger concern and therefore characterized as large. Small enterprises which handle amalgam also include dentists' surgeries.

According to the Dental Trade Association there are currently no Swedish manufacturers of alternative filling materials producing for the Swedish market. The number of companies that distribute or supply such alternatives on the Swedish market is around 40. Of these, around 33 are small enterprises. Members of the Association account for about 90% of the Swedish market for filling materials which are alternatives to dental amalgam (Svedberg, personal communication).

8.3.2 Analytical chemicals and reagents

The main basis for the impact assessment relating to analytical use is the 40 replies received in response to KemI's questionnaire.

It has not been possible to ascertain with certainty, from this database, how many companies are affected nor how many small enterprises may be affected by the proposal. A further uncertainty is the number of unaccredited laboratories that handle mercury in their analytical work. These are not organised into any industry association, and the majority are assumed to be small enterprises. Despite help from the Swedish Standards Institute (SIS) and the Swedish Board for Accreditation and Conformity Assessment (SWEDAC), it has not been possible to identify the number of suppliers and mercury-using companies which may be affected.

In Sweden there are currently about 230 accredited laboratories. Among these are laboratories belonging to local authorities, county administrative boards, universities and national public authorities. In the total, there are about 31 companies, local authorities and universities, which are accredited for mercury analyses in different matrices. The majority of the accredited laboratories belong to large companies or to companies that are part of larger concerns. KemI does not know how many of these 230 accredited laboratories use mercury in their analytical work. In addition to the 230 accredited laboratories, there are about 100 laboratories that perform medical analyses. Most of these are a part of large hospitals that are not characterized as small enterprises.

8.3.3 Seam welding

In Sweden there are currently about 50 users: with 100 seam-welding machines. Of these, about 90% are small enterprises, according to the ASEI (Hörnfeldt, personal communication).

8.4 Financial impacts

Financial impacts are taken to mean charges, costs for changed processes that modified rules can cause, salary costs, and investment in plant and new staff connected to the changeover period and new duties.

8.4.1 Amalgam

One manufacturing company has stated, in its returned questionnaire, that up till now it has only switched to a limited extent to the production of alternative filling materials. Further adaptation costs and investment costs will therefore accrue to the company, if it intends to adapt its manufacturing completely in accordance with the Swedish market's requirements and circumstances.

For the small enterprises engaged in distribution, no adverse financial impacts can be identified, either for those which handle dental amalgam or for the small enterprises that handle alternative tooth-filling materials.

Positive financial impacts may, however, follow for the company or companies that acquire(s) the 2-5% share of the market currently held by amalgam sales.

8.4.2 Analytical chemicals and reagents

No financial impacts other than those, which have already been reported in the impact assessments, can be identified for the small enterprises and laboratories affected.

8.4.3 Seam welding

In total there are 100 seam-welding machines for straight seams in Sweden, of which around half are of Italian manufacture and half of Swiss manufacture. According to the impact assessment, there are currently about 50 small enterprises using around 50 of these machines. According to information from the Association of Swedish Engineering Industries (VI) around 50 more machines are located in a few large companies. The users of the Swiss seam-welding machines have the possibility of modifying the existing straight-seam equipment, while the remainder would need to invest in totally new equipment. Half the companies with Swiss equipment have already modified it at a cost of about SEK 100,000 (10,885 EURO) per machine. Our judgement is that no adverse impacts would follow from our proposals. The capital cost of a new Swiss seam-welding machine for straight seams is about SEK 2 million (217,704 EURO).

In its reply concerning the proposal for general exemptions for seam-welding machines, the Swedish Metalworking Industries' Association agreed, in 1999, with the then proposed transitional period [Sveriges Verkstadsindustrier, 1999]. The transitional period now proposed is the same as in 1999, so in Keml's judgement the

proposal should not mean any significant adverse impacts on the companies affected. The chosen transitional period provides the companies with good opportunities to prepare for possible new investments or modifications of existing equipment.

8.5 Competition

Of importance for competition conditions is, *inter alia*, whether the present market-leading companies will obtain advantages over smaller companies as a result of the new rules. Competition conditions are taken to mean: barriers to entry; market access; possibility of growth; increased competence requirements; better conditions for larger companies than for small ones; the competitiveness of Swedish entrepreneurs; stricter environmental and safety requirements; and any relationships of dependency of small enterprises in relation to large competitors.

8.5.1 Amalgam

For the two Swedish manufacturers of dental amalgam the competitive situation may change as a result of the proposals. One of the manufacturers is a large company, for who a change may mean better conditions as regards competition and market access compared with small competitors in the national market. As a result of the proposals, the two manufacturers will be faced with the decision whether or not to change their manufacturing for the Swedish market. If they choose not to do so, the competitive situation in the international market will not be affected.

A national ban can also mean possibilities for manufacturing as well as distribution companies to grow and achieve increased market shares in the national market, as regards alternative filling materials. The competitiveness of the Swedish companies may be good in relation to other players, since they have already adapted to stricter environmental requirements.

If a company chooses to change its activities this can initially lead to lower profit growth, which can be a particularly sensitive matter for a small company, and can also affect its competitiveness. In the longer term, this may among other things change to positive impacts on competitiveness. For companies that have already switched to alternative filling materials, a ban will produce positive impacts on, *inter alia*, competitiveness.

8.5.2 Analytical chemicals and reagents

It has not been possible to identify any consequences as regards the competitive situation for small companies and small laboratories using analytical chemicals and reagents. (See further in the impact assessment.)

8.5.3 Seam welding

For the use of mercury in seam-welding the competitive situation can be affected differently, depending on whether the company has invested in Italian or Swiss machinery and whether the existing machines have already been modified to be mercury-free. Small enterprises that have invested in Swiss equipment may therefore get a competitive advantage over the companies that have invested in

Italian equipment, which must be replaced. Initially this may lead to lower profit growth, which may affect the competitiveness of the companies that have invested in Italian equipment. In our judgement, however, this cannot be seen to be decisive in determining whether or not a company can be competitive.

8.6 Administrative and practical impacts

Administrative and practical impacts is taken to mean work involved in updating administrative regimes, but also other costs or pressure on resources which small enterprises can experience compared with the current regulatory regime. Examples of such factors are indirect costs such as salary costs, inventories, the changes themselves, learning and training³¹.

The actual expenditure of time for individual small entrepreneurs as a result of our proposals is difficult to estimate, since the uses for which it is proposed to regulate are so diversified and variable in extent, and the situation is different in different industries. According to the Board of Swedish Industry and Commerce for Better Regulation (NNR), one generally needs to start from a model of the costs for the time expended to deal with the administrative burden. The average hourly cost for a company in relation to the administrative impacts as a result of regulation is estimated as SEK 600 (65 EURO). (Hultkvist, personal communication). The general estimate and model take no account of the company's character or category. According to NNR, there are no corresponding figures for how many hours are on average devoted to administrative work as a result of regulatory changes.

The actual costs for the administrative burden depend on whether the company can carry out the work using its own staff, how simply its activities can be changed over to be mercury-free, and other factors. KemI's judgement is, therefore, that it cannot analyse how much time small enterprises will need to devote to administrative work in order to adopt the proposals. A certain amount of time will be required, but KemI's judgement is that the time and the administrative burden are not out of the ordinary. Nor can the possibility be excluded that certain administrative and practical impacts, initially experienced as an administrative burden, can in the long term make the enterprise more efficient and reduce other costs that the normal activities generate.

The proposal for new regulations implies an increased possibility for the authorities to monitor the observance of the rules. The increased responsibilities proposed to keep records are assumed to produce positive impacts. The proposal can also mean positive impacts for small enterprises as regards work with self-monitoring and internal auditing of their own activity. The administrative burden that may arise for individual small enterprises can be reduced via a distributed responsibility for work

³¹ According to NNR and information from the OECD, companies with fewer than 20 employees can have costs per employee five times as high in order to conform to the requirements laid down in tax, environmental and labour-law legislation. Generally speaking, companies' costs to administer legal regulations are considerable, and according to the OECD amount to about SEK 30,000 (3266 EURO) per employee per annum for companies with one to nine employees.

on self-monitoring and internal auditing in the industry, and increased cooperation between companies.

8.6.1 Amalgam

For dental surgeries that have already adapted their activity according to the proposal, and gone over to treating patients with alternative filling materials, no administrative or practical impacts are expected. For the dental surgeries that account for the estimated 2-5% of filling work carried out using amalgam, certain administrative and practical impacts may follow.

For small enterprises in the dental trade, no significant administrative or practical impacts can be assumed, since alternative filling materials have already been developed and are established in the market.

8.6.2 Analytical chemicals and reagents

In future, many small laboratories may need to buy in services from larger laboratories. This is, however, a service which many small enterprises with their own laboratories—and small enterprises without—already purchase, so KemI's judgement is that they should not experience an increased cost or further administrative burden as a result of the proposals.

Pharmacopoeia methods are regulated in Swedish legislation via the MPA's Statute Book and must be followed. Among the pharmacopoeia methods are ones using instruments that contain metallic mercury and others that need mercury compounds. The fact that Swedish regulatory regime differentiates between instruments and mercury compounds could mean that the rules are somewhat more complicated for the practitioners to adhere to. The number of applications for exemptions from the pharmaceuticals industry has, however, been very limited over the last 10 years, so KemI judges that this ought not to result in any adverse administrative impacts on the small laboratories affected.

8.6.3 Seam welding

No impacts other than those already indicated in the report have been identified as regards the companies that use seam-welding machines.

8.7 Other impacts

If the decision is taken to implement the proposal, the Swedish national regulation will go further than the regulatory regime for mercury, which applies within the EU. When a public authority or government chooses to go further than a decision that has been taken by one of the EU's institutions this is commonly called "gold plating". Current Swedish legislation on mercury does go further than corresponding EU regulation, and under the current regulatory regime no information has been received about problems resulting from the Swedish "gold plating". Nor did any such indications come in during the consultation on the draft proposals in connection with the notification to the Commission in 2000. And since no complications of this kind have been brought forward during the course of the present investigation, the KemI's assessment is that the proposal will not mean

changed conditions for Swedish companies' operations, compared with companies operating in other EU countries. For example, as regards competition, market share, or more difficult administrative requirements.

Positive impacts, which a national ban may bring about for small enterprises, are that workplaces would provide a safer working environment, with simpler procedures, as a result of reduced use of mercury and reduced risks of exposure to mercury. This can affect efficiency and productivity and also reduce costs, including environmental costs.

8.8 Conclusions from Simplex analysis

Of great importance to the extent of impacts on companies in general and for small enterprises in particular is the transitional period for new rules. The transitional period proposed should therefore be reasonable, taking particular account of the situation of small enterprises. If the new legislation creates new demands for state enforcement an adjustment to the transitional period is important.

In the case of the proposed ban on mercury, Keml's judgement is that no special time-limited exemptions for small enterprises are justified, beyond those contained in our proposal. The time-limited exemptions will, in our judgement, be sufficient even for small enterprises. The recommended transitional period is been proposed to take account of the activities of small, medium and large enterprises.

9 CONCLUSIONS AND DISCUSSION

Mercury is one of the most hazardous environmental toxins and is a threat to human health and the environment. Mercury cannot be broken down but accumulates in soil, water and living organisms. The more mercury is supplied to society the more the levels in the environment increase. It is therefore of great importance that the use and release of mercury should be eliminated. The purpose of the ban is to reduce the supply of mercury to society, and therefore to the environment, as much as possible.

KemI proposes that a general ban should be introduced to prohibit mercury³² or goods that contain mercury *being placed on the Swedish market or exported commercially* from Sweden. Goods that are already on the market, or in use, may continue to be used. KemI has identified a number of areas where harmonized EC legislation makes it very difficult to introduce national rules, and which are therefore exempted from the ban. This applies, for example, to batteries, light sources and vehicles.

In addition to this, KemI has made the judgement that there is a need for time-limited exemptions from the ban for some uses. This applies, for example, to mercury compounds used for analysis; metallic mercury in seam-welding wheels; and tracking devices for wildlife. In hospital dentistry, there may be a few situations where for special medical reasons using amalgam is the only alternative to extracting the tooth. The National Board of Health and Welfare and KemI therefore propose an exemption for the use of amalgam on adult patients in hospital dentistry. For chlor-alkali production, KemI judges that an exemption for the use of mercury until 2009 in accordance with the government's previously established objectives and Sweden's international commitments is reasonable. Assuming that the proposal comes into force KemI intends to amend its regulations in conformity with what has emerged in this investigation. Companies and users will thus get time to adapt to the new rules. The impacts of the proposal are therefore in reasonable proportion to the positive effects it has on the environment.

Mercury can occur naturally, e.g. in coal, ores and ore concentrates. These products have been expressly excluded from the ban, since the possibilities for and impacts of such a ban have not been investigated in detail as part of the commission. KemI considers that there are strong objective reasons to supplement the proposed bans with export restrictions to also cover the mercury contained in raw materials such as ore and ore concentrate. For example, a responsibility could be introduced that mercury obtained as a by-product from Swedish ore and ore concentrate must be returned for final disposal in Sweden. In view of the interpretations and scope which KemI has applied to the commission, the impacts of regulating exports of ore concentrate have not been investigated, and KemI is therefore not putting forward any proposals to address that issue now. It is important that a separate investigation of this be carried out.

As regards the presence of mercury in coal, other restriction measures directed towards the use of fossil fuels or direct emission limits can also be considered as ways of reducing mercury emissions.

³² By "mercury" is also meant chemical compounds and preparations containing mercury.

9.1 "A non-toxic environment"

A general ban will mean that the legislation more clearly reflects the national environmental-quality objective "A non-toxic environment" and subsidiary objective No 3 implies, *inter alia*, that newly produced goods should as far as possible be free from mercury. The proposed general ban would lead to Sweden having achieved as much as KemI judges to be possible at the national level.

The largest use in products which would remain, if the proposed general ban came into force, is mercury in light sources. These are exempted from the mercury ban in the EU's Electronics Directive [2002/95/EC], but from 1 July 2006 there will be requirements for maximum levels of mercury in low-energy lamps and fluorescent tubes. Some of these products already contain low levels of mercury, but it is uncertain whether this is true of all low-energy lamps and fluorescent tubes on the market in Sweden. There is therefore a possibility that the requirements in the Directive may lead to a reduction in the annual supply of mercury to society within a few years. The exemptions in the Directive will be reviewed in 2005.

In certain cases, the use of mercury can lead to conflicts between different environmental objectives or between environmental considerations and human health. An example is the use of mercury in low-energy lamps, which are regarded as assisting the environment since large quantities of energy can be saved. Mercury is also necessary in the analysis of mercury in, for example, environmental monitoring. Currently, mercury is also needed for certain medical diagnoses.

9.2 Impacts of the proposal

9.2.1 *Reduced quantities of mercury in society and the environment*

It is calculated that the proposed general ban will lead to a drop in the annual new supply of mercury to society in goods and products from about 340 kg in 2003 to about 260 kg per annum³³. When the majority of the proposed exemptions have expired, it is calculated that the supply of mercury will decrease by a further about 70 kg per annum to about 190 kg. It is principally the bans on amalgam and analytical chemicals that lead to the reductions. In Sweden the use of amalgam has been identified as the single largest source of mercury in sludge from sewage treatment plants, and crematoria are a major source of emissions of mercury to the air. A ban on amalgam is therefore important from an environmental point of view. The use of mercury compounds in analyses leads to mercury-containing waste, which must be dealt with. A ban in accordance with the proposal means that these quantities will fall, and in the long term be minimized.

In accordance with the government's previously established objectives and Sweden's international commitments, an exemption is proposed for the use of mercury in chlor-alkali production until 2009. When the exemption expires, the about 400 tonnes of mercury used in the processes must be dealt with as hazardous waste and

³³ The calculated reduction is based on the assumption that the proposal for exemptions for the use of amalgam corresponds to about 20% of the quantity of mercury sold for amalgam in 2003.

prepared for final disposal. The process-related emissions will also cease. In 2002 the companies reported discharges of about 38 kg of mercury to the air, about 2 kg to water and about 4 kg as residual quantities in the products.

9.2.2 Impacts for industry and commerce

In KemI's judgement, Swedish companies have the possibility of complying with the proposed regulation of mercury. For those industries and companies where the impacts analysis has indicated significant adverse impacts, time-limited exemptions from the general ban have been proposed to facilitate the companies' change-over and the development of alternative methods.

The transitional period proposed also takes account of the situation of small enterprises. In KemI's judgement the proposal will not lead to any further special impacts on small enterprises.

The increased obligation to keep records for anyone who imports, manufactures, sells or professionally uses mercury or goods containing mercury that are exempted from the ban can facilitate the companies' chemical-control procedures, but may also be understood as enforcement of an administrative burden. In certain cases it may, however, be possible to distribute the responsibility within the industry and in that way reduce the administration for individual companies.

9.2.3 Handling of dispensations

The proposal contains a continued authority for KemI to grant exemptions from the general ban in individual cases if there are exceptional reasons. An authority is proposed for the Swedish EPA to grant dispensations from the ban on the export of mercury-containing waste if there are special reasons, with the possibility of imposing the condition that the mercury be returned to Sweden for final disposal.

The possibility for KemI to grant dispensations has played an important part in progress with and acceptance of the current rules for mercury. If a general ban on mercury in accordance with the proposal comes into force, the number of dispensations dealt with—principally by KemI—will probably increase temporarily. It is, however, difficult to estimate how many dispensations may be involved. Mercury is used in many different fields and in many specialist applications. It is therefore not certain that this investigation has covered every single area that will be covered by a general ban, and this may lead to a number of applications for dispensations. It is also difficult to predict what development of alternative methods will occur during the years when it is proposed that certain uses are exempted from the ban. KemI judges that an increase in the number of applications for dispensations will, on the whole, be manageable and the benefits from the proposal outweigh the drawbacks arising from this aspect.

9.2.4 Enforcement

A general ban means that what is not expressly exempted from the ban is banned. It therefore covers any new use of mercury and various odd uses, which the authorities sometimes come across. KemI judges that the enforcement of the new rules will in certain respects be easier than in the case of the previous mercury rules. Among

other things, the paragraph stating that goods may be used only if they have come into use since 1 January 1995, which in practice has been hard to check, disappears. An increased obligation to keep records for those who professionally import, manufacture, sell or use mercury, or goods containing mercury which are exempted from the ban, is also judged to be able to facilitate enforcement of the rules.

Control of the import of equipment containing mercury is difficult. Increased cooperation between the supervisory authority and the Customs Authority is probably needed for effective enforcement.

9.2.5 Information needs

There will be a need for public authorities to provide information on the new rules for mercury. There is already a lack of knowledge about what current legislation does and does not cover. Part of the misunderstanding can probably be traced back to work on the notification of new rules to the EU, which was carried out in 1999 and 2000 (see Para 2.2).

9.3 Mercury stored in society

Button-cell batteries, fluorescent tubes and low-energy lamps, for example, will still contain mercury after the general ban has been introduced. These consumer products risk ending up in ordinary refuse. To reduce the environmental risks it is important that the consumers are now and then informed about how this waste is to be handled and that they find its collection practical and available as an everyday thing.

Within society, there is up to an estimated 30 tonnes of mercury in existing instruments and equipment and about 10 tonnes of metallic mercury in store (see Para 3.3). There are risks that this mercury will contaminate the environment in the future. It is therefore important that mercury is dealt with in an environmentally safe way when the equipment is replaced and the instruments are scrapped. From 1994 to 1999 the Swedish Environmental Protection Agency (SEPA) carried out a program for improved collection of mercury-containing goods on behalf of the government. The program included a project for the identification and collection of mercury and the labelling of goods which contain mercury and are still used [Naturvårdsverket, 1999]. It is to be hoped that this will lead to waste being dealt with correctly and to the risk of future emissions being minimised.

Large quantities of mercury are also stored in society in the form of amalgam fillings. It is estimated that 74% of adult Swedes have amalgam fillings [SOU 2003:53] and the quantity of mercury involved has been estimated as 40-60 tonnes (Para 3.3). About 70 % of all deceased in Sweden are cremated; around half the crematoria use flue-gas scrubbing [Naturvårdsverket, 2004]. This means that 28-42 tonnes of mercury from the deceased will either be emitted to the air or trapped in the flue-gas scrubbers, and must be dealt with for final disposal.

The number of fillings per individual is unequally distributed in the population. Over the coming 10-30 years mercury emissions from crematoria will probably increase, because the extra large 1940s generation have significantly more amalgam per individual than earlier generations. In the Netherlands it is estimated that emissions from crematoria will double by 2020 if scrubbing is not introduced [OSPAR, 2003]. It is important to work for significantly more crematoria to install

flue-gas scrubbing or other techniques to eliminate mercury emissions. In the event that it is still judged to be economically unreasonable to require that best available technology be used, when applications are examined, there will be a need to consider if there are other ways to eliminate mercury emissions. KemI considers that a dialogue regarding the possibilities for eliminating mercury emissions from crematoria in which ethical, environmental, economic and technical aspects are weighed against one another should be held with all the interested parties.

9.4 On-going work in the EU and internationally

Despite Swedish efforts to restrict the use of mercury and emissions, deposition of mercury over Sweden is still great because of long-distance air transport, mainly from the rest of Europe. Mercury levels in freshwater fish exceed the WHO/FAO limit in half of Sweden's lakes. This means that women who plan to have a baby soon, are pregnant or are breast-feeding are recommended not to eat certain species of freshwater fish, to avoid effects on the foetus or new-born baby. According to the environmental-quality objective "A non-toxic environment" the levels of mercury in the environment should be close to the background level within a generation. On the way there, the objective is first and foremost to get mercury levels in fish down to levels at which it can be eaten without risk to human health, and levels in forest soils down to levels which do not put the functioning of the ecosystem at risk.

To reduce the burden of mercury in the environment, it is necessary with regional and global restrictions on emissions of mercury and on the use in products. Mercury in products can be emitted to the air during the use phase, or after scrapping via waste incineration, or from landfills. The contribution to total anthropogenic atmospheric deposition of mercury is not negligible. In 1997 the Swedish Environmental Research Institute Ltd. (IVL) estimated that mercury in batteries, measuring instruments, electrical equipment and light sources in Europe contributes 10-14% of mercury deposition in Scandinavia. The greatest contribution comes from light sources and electrical equipment [Kemikalieinspektionen, 1997b]. Amalgam was not included in the investigation. Estimates from 2002 show that amalgam is the single largest use of mercury in the EU: about 70 tonnes per annum [Concorde East/West Sprl, 2004].

Before the end of 2004 the European Commission will present an action strategy for mercury to protect the environment and human health from emissions of mercury, taking account of production, use, waste handling and emissions. It is to be hoped that the strategy will result in further regulation of emissions and use of mercury within the EU.

Certain EU countries are key players in the global trade in mercury [Concorde East/West Sprl, 2004]. An important question is how the mercury (up to 15,000 tonnes) no longer required by the European chlor-alkali industry when it converts to mercury-free operation is to be prevented from reaching the global market. Otherwise, there is a great risk that the mercury will end up in developing countries to be used in products and processes that are not accepted in Europe, for example, small-scale gold extraction. A report laid before the Nordic Council of Ministers' International Workshop on Mercury in March 2004 shows that it is possible to ban exports of mercury from EU countries within the framework of existing EU legislation [Öberg, 2004]. Such legislation would also prevent mercury from

exported Swedish ore concentrate, produced as a by-product of zinc smelting, being sold on the global market (see Para 7.1.2).

Based on the key findings in the Global Mercury Assessment Report [UNEP, 2002], the UNEP Governing Council concluded, in February 2003, that mercury is a global environmental problem that warrants further international action. In February 2005 UNEP will consider the need for and design of measures against mercury at the global level. Countries have been asked to give their opinions on the issue, and Sweden's views were submitted in June 2004.

Mercury is also a current issue within LRTAP, since a heavy-metal protocol came into force in December 2003. Mercury emissions and deposition are charted within LRTAP. Models are being developed to link mercury deposition on forest soil to the critical load³⁴ for forest soil and mercury levels in freshwater fish. This work is expected to be completed within a few years and lead to a revised heavy-metal protocol with stricter restriction measures. A proposal containing measures to be taken, including measures against the use of mercury in products, is expected to be complete during 2005.

³⁴ "Critical load" is the highest supply which can be tolerated, in the present state of knowledge, without causing damage.

GLOSSARY OF NAMES AND ABBREVIATIONS

Association of Hospital Dentists	Sjukhustandläkarföreningen
Association of Swedish Engineering Industries	Teknikföretagen
Biomedical Dental Centre	Biomediciniskt Dentalcentrum
Board of Swedish Industry and Commerce for Better Regulation (NNR)	Näringslivets Regelnämnd (NNR)
BOD	Biochemical Oxygen Demand
COD	Chemical Oxygen Demand
Dental Material Investigation	Dentalmaterialutredningen
DOC	Dissolved Organic Carbon
FAO	UN Food and Agriculture Organisation
Knowledge Centre for Dental Materials	Kunskapscentrum för dentala material (KDM)
LRTAP	Long Range Transboundary Air Pollution. Convention within the UNECE which contains, inter alia, a heavy metal protocol
Medical Products Agency (MPA)	Läkemedelsverket
Ministry of Health and Social Affairs	Socialdepartementet
Ministry of the Environment	Miljödepartementet
National Board of Health and Welfare	Socialstyrelsen
National Board of Trade	Kommerskollegium
National Dental Service	Folktandvården
National electricity grid company	Svenska Kraftnät
National Food Administration (NFA)	Livsmedelsverket
National Social Insurance Board	Riksförsäkringsverket
Research Group for Community and Information Studies	Forskningsgruppen för samhälls- och informationsstudier (FSI)
SIS, Swedish Standards Institute	SIS
SOU	Swedish Government Official Reports
Specialist Clinic for Anaesthesia	Specialistkliniken för Narkos
Statistics Sweden (SCB)	Statistiska Centralbyrån (SCB)

Stockholm Environment and Health Administration	Miljöförvaltningen i Stockholm
Stockholm Water Company	Stockholm Vatten AB
Swedish Board for Accreditation and Conformity Assessment (SWEDAC)	SWEDAC, Styrelsen för ackreditering och teknisk kontroll
Swedish Chemicals Inspectorate (KemI)	Kemikalieinspektionen (KemI)
Swedish Dental Association	Tandläkarförbundet
Swedish Dental Trade Association	Föreningen Svensk Dentalhandel
Swedish Electricity Industry Association	Svensk Energi
Swedish Environmental Code	Miljöbalken
Swedish Environmental Protection Agency (SEPA)	Naturvårdsverket
Swedish Environmental Research Institute Ltd. (IVL)	IVL Svenska Miljöinstitutet AB
Swedish Federation of County Councils (FCC)	Landstingsförbundet
Swedish National Rail Administration	Banverket
Swedish Society for Nature Conservation (SSNC)	Svenska Naturskyddsföreningen (SNF)
Swedish Waste Treatment Company	Sydkraft SAKAB AB
Swedish Work Environment Authority (SWEA)	Arbetsmiljöverket
The major Swedish electricity utility	Vattenfall
The Swedish Disability Federation (HSO)	Handikappförbundens samarbetsorganisation (HSO)
The Swedish Metalworking Industries' Association (their name is since May 2003 Association of Swedish Engineering Industries)	Sveriges Verkstadsindustrier (i maj 2003 bytte de namn till Teknikföretagen)
TOC	Total Organic Carbon
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
WHO	World Health Organisation

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In addition to the references given below, a large number of questionnaires from interested parties have been used in the investigation. When information from several questionnaires has been weighed together in the impact analysis, all those references are not given below.

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Annex 1

Ordinance (1998:944) Concerning Prohibitions etc in Certain Cases in Connection with the Handling, Import and Export of Chemical Products

Section 8

Mercury and chemical compounds and preparations containing mercury may not be commercially exported from Sweden.

Section 9

The following goods may not be commercially manufactured or sold if such goods contain mercury:

1. clinical thermometers;
2. other thermometers;
3. level switches, pressure switches, thermostats, relays, circuit breakers and electrical contacts; and
4. measuring instruments other than as set forth in 1-3 above.

The goods may not be commercially imported from countries which are not members of the European Union. The goods may not be commercially exported from Sweden.

The Swedish Chemicals Inspectorate may issue regulations such that the prohibitions shall also apply in respect of equipment in which a good which is set forth in paragraph 1, sub-paragraph 3 is a constituent element.

Section 10

Goods referred to in Section 9 may only be used if such were in use in Sweden prior to 1 January 1995.

Section 11

The Swedish Chemicals Inspectorate may issue regulations regarding exceptions from prohibitions set forth in Sections 8 or 9, paragraphs one and two, and Section 10, where special cause exists therefor.

The Swedish Chemicals Inspectorate may, in individual cases, grant exemptions from the prohibitions set forth in Section 8-10, where exceptional reasons exist therefor.

Section 12

Packaging and packaging components may not be manufactured, offered for sale, or transferred where the total concentrations of lead, cadmium, mercury, and hexvalent chrome exceed the following values:

1. 600 µg/g,
2. 250 µg/g, after 30 June 1999;
3. 100 µg/g, after 30 June 2001.

Special provisions are set forth in Sections 3 and 4 in respect of use of cadmium substances for surface treatment or as stabilisers or as colouring agents. The first paragraph does not apply to packaging which was in use prior to December 1994.

Annex 2

The Swedish Chemicals Inspectorate's Regulations (1998:8) on Chemical Products and Biotechnical Organisms

Chapter 9, Mercury-Containing Products

Exempted products

Section 15

In derogation of the prohibitions in Section 9 of Ordinance (1998:944) on Prohibitions etc. in Connection with Handling, Importing and Exporting Chemical Products (Certain Cases), products listed in Annex 3 may be imported, manufactured and sold as there provided.

In derogation of the prohibitions in Section 10 of the Ordinance, a product listed in Annex 3 may be used as there provided, even if the product was not in use before 1 January 1995. The same shall apply to the use of a product containing mercury, for any purpose for which, in the individual case, the National Chemicals Inspectorate has authorised importation, manufacture or sale of the product.

Reintroduction after repair and calibration

Section 16

In derogation of the prohibitions in Section 9, subsection two of the Ordinance (1998:944) on Prohibitions etc. in Connection with Handling, Importing and Exporting Chemical Products (Certain Cases), such products may professionally be taken out of Sweden for repair or calibration and reintroduced to Sweden.

The prohibition in Section 8 of the Ordinance shall not prevent mercury-containing waste from being taken out of Sweden if the Swedish Environmental Protection Agency has authorised the transport pursuant to the provisions about transboundary transport of waste.

Obligation to keep records

Section 17

Anyone importing, manufacturing or selling such products as are referred to in Annex 3 shall keep records of:

1. the date of import, professional manufacture or sale;
2. the number of products imported, manufactured or sold;
3. the amount of mercury contained in products imported, manufactured or sold;

4. if the products have been sold, the name and address of the buyer, or otherwise what has happened to them.

The obligation to keep records also applies when products listed in Annex 3 are imported from a Member State of the European Union.

Section 18

Records shall be kept in a separate book or kept together in such a way that they can be easily checked.

Section 19

The person obliged to keep the record shall retain the same for as long as he carries on any recordable activity and for three years thereafter.

Regulation 1998:8, Annex 3: Products exempted from the prohibitions in the Ordinance 1998:944.

Product and area of application	May be imported, manufactured and sold for the indicated use until	May be imported, manufactured and sold as <i>spare parts</i> for the indicated use
<i>Thermometers</i>		
1. Thermometers for professional meteorological, hydrological and oceanographical monitoring, and for instruction use in the teaching of meteorology, hydrology and oceanography	31 December 1996	—
2. Thermometers for flashpoint determination as provided in Directive 67/548/EEC	31 December 2003	—

Product and area of application	May be imported, manufactured and sold for the indicated use until	May be imported, manufactured and sold as <i>spare parts</i> for the indicated use
<i>Relays, electrical contacts</i>		
3. Relays for flashers in safety apparatus for railway traffic, for opening bridges and for locks for sea traffic.	31 December 1993	31 December 2003
4. Relays with mercury wetted contacts with not more than		
a) 1.5 g of mercury per contact	31 December 1994	31 December 2004
b) 0.05 g of mercury per contact.	31 December 1997	31 December 2007
5. Relays with mercury wetted contacts for industrial equipment with not more than 1.5 g of mercury per contact and intended for professional fitting	31 December 1997	31 December 2007
6. Electrical contacts for indication of inclination in military vehicles and craft, in rescue vehicles and in vehicles for public transport.	31 December 1993	31 December 2003
7. Electrical contacts for indication of position for professional fitting in personal alarm systems.	31 December 1995	31 December 2005
8. Electrical sensor contacts for anti-lock braking for professional fitting in motor vehicles	31 December 1996	31 December 2006

Product and area of application	May be imported, manufactured and sold for the indicated use until	May be imported, manufactured and sold as <i>spare parts</i> for the indicated use
9. Electrical sensor contacts for airbags for professional fitting in motor vehicles.	31 December 1996	31 December 2006
10. Electrical sensor contacts, ignitron tubes, for professional fitting in industrial apparatus.	—	31 December 1997
11. Electrical sensor contacts for professional fitting of car-belt stretchers variable suspension systems and automatically activated roll-over bars in vehicles	—	31 December 2001
<i>Other measuring instruments</i>		
12. Barometers for professional meteorological monitoring.	31 December 1996	—
13. Manometers for professional control and calibration at stations for weather observations.	31 December 1996	—
14. Manometers for physiological control and calibration.	31 December 1994	—
15. Strain gauges with not more than 1.5 g of mercury, for physiological use.	31 December 2003	—
16. Manometers for cell counting instruments for hospital laboratories.	—	31 December 2007

Product and area of application	May be imported, manufactured and sold for the indicated use until	May be imported, manufactured and sold as <i>spare parts</i> for the indicated use
17. IR instruments for professional measuring of thermal radiation.	31 December 1997	—
IR detectors for such instruments.	—	31 December 2007
18. Porosimeters for professional measuring.	31 December 1995	—
19. Polarographs for professional measuring.	31 December 1997	—
Electrodes for such instruments.	—	31 December 2007

Annex 3

Mercury supplied to Swedish society in chemical products and goods 1991/92, 1997 and 2003

Table. Mercury supplied to Swedish society in chemical products and goods, in kg. Data for the years 1991/92 and 1997 originates from KemI Report No 5/98.

	1991/92	1997	2003
Thermometers	328 ¹	0,13 ²	0,07 ² (1-2) ¹³
Electrical components	4500 ³	3 ²	- ²
Measuring instruments		17 ²	20 ²
Batteries	2300 ⁴	800 ⁴	<24 ⁴
Light sources	300 ⁵	150 ⁶	121 ⁶
Neon tubes		30 ⁷	18 ⁷
Equipment		40-50 ⁸	
Dental amalgam	1700 ⁹	980 ¹⁰	103 ¹⁰
Medicinal products, veterinary medicinal products and cosmetics		>0,2 ¹¹	0,2 ¹¹
Analytical chemicals		<45 ¹²	53 ¹⁴
Total	>9100	2060	340

Metallic mercury

Import (SCB)	56 000	39 000	3000
National trade	12 000 ¹⁵	580 ¹²	
Export (SCB)	59 000	0-1000	1000

¹ KemI PM 6/96 ² information on exemptions ³ incl. measuring instruments, KemI PM 6/96 ⁴ Swedish Environmental Protection Agency ⁵ KemI report 8/94 ⁶ LAMPA 1998; 2004 amended to cover the market ⁷ Association of illuminated advertising (Ljusreklamförbundet) 1998; 2004 amended to cover the market ⁸ Kemiinformation AB, 1998 ⁹ Information referred to in "Arbete och Hälsa" 1998;2, and in KemI PM 4/96 ¹⁰ The sector office & Swedish Dental Trade Association, 1998; 2004 ¹¹ Swedish Medical Products Agency & Swedish Pharmacies Ltd (Apoteksbolaget) ¹² according to Section 17, permit at county councils (see 3.1.3) ¹³ Sale of thermometers for flashpoint determination, Göteborgs Termometerfabrik AB (supplier), 2004 ¹⁴ Chemical suppliers of analyses and reagents (VWR International AB, Hach Lange AB, Bergman Labora AB and Tamro Medlab AB) ¹⁵ KemI 1996.

Annex 4

Legal analysis of EU directives and regulations which regulate mercury

The following is a summary of the directives and regulations which have been identified in this commission and which regulate mercury. An analysis of the possibilities and obstacles regarding the introduction of a national ban on mercury has been made for each directive and regulation.

- The Battery Directive
- The Limitations Directive
- The Biocidal Products Directive
- The Plant Protection Products Directive
- The Directive on in vitro diagnostic medical devices
- The Directive on type-approval of motor vehicles
- The Directive on end-of-life vehicles
- The Electronics Directive (RoHS Directive)
- The Export and Import Regulation
- The Packaging Directive
- The Cosmetics Directive
- The Toy Safety Directive
- The Medicinal Products Directive and Regulations
- The Medical Devices Directive

The Battery Directive

Directive 91/157/EEC on batteries and accumulators containing certain dangerous substances

The aim of the regulation is a harmonisation of the national regulations of the Member States, the legal basis of the Directive being Article 95 of the EC Treaty. That the aim of the rules is harmonisation is also apparent from Articles 1 and 9 of the Battery Directive. According to Article 1, the aim of the Directive is to approximate the laws of the Member States. Article 9 states that Member States may not impede, prohibit or restrict the marketing of batteries and accumulators covered by the Directive if they conform to the provisions of the Directive. The Directive covers effects on the natural environment.

Member States shall forbid the marketing of batteries and accumulators containing more than 0.0005 % of mercury by weight, including cases where such batteries and accumulators are contained in appliances. Button cells and batteries consisting of button cells with a content of a maximum of 2% mercury by weight are excluded from the ban. An annex to the Directive specifies the batteries covered by the Directive.

On 24 November 2003, the Commission adopted a proposal for a new battery directive but this does not involve any change in previous provisions regarding the mercury content of batteries. The Directive covers all types of batteries (Article 2).

The aim of the present Battery Directive is a harmonisation of the national regulations and takes environmental effects into consideration. This means that stricter national regulations can only be introduced by reference to the environmental guarantee.

The Directive was incorporated into Swedish law by Ordinance (1997:645) on batteries.

The Limitations Directive

Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations

According to the Limitations Directive³⁵ mercury compounds may not be used as substances and constituents of preparations intended to prevent the fouling by micro-organisms, plants or animals of the hulls of boats, cages, floats, nets and any other appliances or equipment used for fish or shellfish farming or any totally or partly submerged appliances or equipment and for the preservation of wood. This control is applied in Sweden by the rules on authorisation procedure for pesticides.

According to the Limitations Directive, mercury compounds may not be used as substances or constituents of preparations intended for use in the impregnation of heavy duty industrial textiles and yarn intended for their manufacture. This part of the Directive is not clearly specified in Swedish legislation and this is a matter which KemI is reviewing.

In addition, mercury compounds may not be used as constituents in chemical products intended for use in the treatment of industrial process water. This regulation was incorporated into Swedish law by Chapter 10 of KIFS 1998:8³⁶ after authorisation in Ordinance (1998:941) on chemical products and biotechnical organisms.

³⁵ Council Directive 89/677/EEC of 21 December 1989 amending for the eighth time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the member states to restrictions on the marketing and use of certain dangerous substances and preparations

³⁶ National rules on bans on mercury are also included in Ordinance (1998:944) on Prohibitions etc. in certain cases in connection with the handling, import and export of chemical products

The Limitations Directive³⁷ specifies that pentachlorophenol shall not be used in a concentration equal to or greater than 0.1 % by weight in substances or preparations placed on the market. The European Court³⁸ has laid down that the limit specified in the Limitations Directive is applicable to pentachlorophenol, its salts and esters used alone or as a component of preparations, but not to products treated with these substances or preparations. Member States are therefore free to establish independent limit values for the latter. The regulation of mercury within the scope of the Limitations Directive thus only involves a harmonisation of such use of mercury as is specifically mentioned. Other areas of the use of mercury fall outside the area harmonised by the Limitations Directive. This means there is a possibility for Member States to introduce national regulations with regard to these areas of usage. A regulation within the Limitations Directive which implies that a certain amount of a substance may be present does, however, involve harmonisation of national rules regarding that particular usage. In these cases it is not possible for a Member State to impose stricter national rules. Such regulation of mercury as is covered by the Limitations Directive does not therefore prevent a national ban on the handling of mercury, since the regulation of mercury in the Limitations Directive means a total ban on the regulated usage and that other areas of mercury usage fall outside the area harmonised by the Limitations Directive.

The Biocidal Products Directive

Directive 98/8/EC concerning the placing of biocidal products on the market and regulation (EC) No 2032/2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC

Member States shall prescribe the placing on the market and the use of a biocidal product only if it has been approved in accordance with the Directive. It is however permissible to release certain low-risk products only after registration. A biocidal product can be approved or registered if the active substance which it contains is included in one of the annexes to the Directive.

The Commission's Regulation lists the active substances which have been registered or identified in accordance with a procedure in Regulation 1896/2000. These substances will either be phased out from the market or examined in order possibly to be included in one of the annexes to the Directive regarding the active substances which biocidal products may contain. Neither mercury nor any of its compounds is included in any of these lists.

³⁷ Council Directive 91/173/EEC of 21 March 1991 amending for the ninth time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the member states to restrictions on the marketing and use of certain dangerous substances and preparations (also amended by Directive 1999/51/EC)

³⁸ Judgement of the Court (Sixth Chamber) of 1 October 1998. Willi Burstein against Freistaat Bayern. Request for preliminary ruling: Bayerisches Verwaltungsgericht Regensburg Germany. Case C-127/97.

Mercury is thus not included among the active substances which have been identified and registered. It is therefore possible, on the basis of the Biocidal Products Directive, to introduce a national ban on mercury.

Directive on ban on plant protection products

Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances

According to Articles 1 and 3, the Directive involves a direct ban on the placing on the market and use of plant protection products containing, *inter alia*, mercury³⁹. The Directive has its legal basis in Article 100, which provides that the Council may decide upon measures appropriate to the economic situation. The preamble of the Directive indicates that the use of plant protection products is one of the most important methods of protecting plants and plant products and of increasing the productivity of agriculture. Such use can, however, involve risks for man and the environment. In the case of certain plant protection products, these risks are so great that their use can no longer be allowed. In order to eliminate these obstacles to trade, there appears to be justification for introducing a basic principle which involves prohibition of the use of all plant protection products containing active substances which can give rise to harmful effects on health or to unacceptable effects on the environment.

The Directive contains a total ban on the use of mercury in plant protection products and therefore does not constitute an obstacle to the introduction of a national ban on mercury⁴⁰.

Directive on in vitro diagnostic medical devices

Directive 98/79/EC on in vitro diagnostic medical devices

The Directive has its legal basis in Article 95 of the EU Treaty and is a new-approach directive. That means that the area is harmonised. This is expressed in, for example, Article 4 of the Directive, where it is explicitly stated that the Member States may not prevent products being placed on the market or put into service if they have been CE marked in accordance with the rules in the Directive.

The rules and requirements in the Directive have been incorporated into Swedish law by the act (1993:584) on medical devices, Ordinance (1993:876) on medical devices and those regulations which, under the provisions of the ordinance, have

³⁹ Mercury oxide, mercury chloride (calomel), other inorganic mercury compounds, alkylmercury compounds, and alkoxyalkyl- and arylmercury compounds (Appendix to the National Chemicals Inspectorate's Regulations, KIFS 1998:8).

⁴⁰ According to Article 5, plant protection products containing mercury may be used for research or analysis purposes.

been issued by the Medical Products Agency and the National Board of Health and Welfare⁴¹.

In order to be CE marked, an in vitro diagnostic medical device shall be suitable for its use. Most in vitro diagnostic devices undergo a manufacturer's declaration in accordance with LVFS 2001:7, Appendix III. In the case of products intended for self-testing and "risk products" listed in LVFS 2001:7 Appendix II, lists A and B, the process shall be carried out in cooperation with a registered body. The final responsibility for ensuring that the product complies with the product requirements is borne by the manufacturer, who also affixes the CE mark on the product.

In contrast to the provisions of Directive 93/42/EEC, the essential requirements for in vitro diagnostic devices include requirements that the products shall be constructed and manufactured in such a way as to facilitate safe waste disposal⁴².

A limited number of diagnostic test systems contain preservatives thiomersal to ensure that unwanted growth of micro-organisms does not take place in reagents, which in turn can cause deficient/abnormal product properties. The concentration of these mercury salts is very low.

The Directive on in vitro diagnostic medical devices is a new-approach directive and means a harmonisation of in vitro diagnostic medical devices. The possibilities for Sweden to prevent CE marked medical devices from being placed on the market or put into service within the country are therefore limited. The effects on the natural environment during production and use of in vitro diagnostic medical devices are taken into account in the essential requirements with which all in vitro diagnostic products must comply. A Member State cannot therefore introduce a national ban on the handling of mercury and refer to the fact that the Directive does not regulate effects on the natural environment.

Directive on type-approval of motor vehicles

Directive 70/156/EEC on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers

The Directive is based on Article 95 of the EC Treaty and takes environmental aspects into consideration.

Type-approval means the procedure whereby a Member State certifies that a vehicle type, a system or a component or a separate technical unit satisfies the relevant requirements in the Directive or in any of the separate directives listed comprehensively in a list included in the Directive (Annex 4). A manufacturer who has been granted a type-approval shall complete a certificate of conformity for all vehicles.

⁴¹ LVFS 2001:5, LVFS 2001:6, LVFS 2001:7, LVFS 2001:8, LVFS 2002:2, LVFS 2003:3 and SOSFS 2001:12.

⁴² Directive 98/79/EC Annex 1 B item 3.5

It is clear from the practice of the Court of Justice⁴³ that there are obstacles to the introduction of national regulations in which, for registration of vehicles covered with a valid Community certificate of conformity, additional national requirements are imposed. The Directive states that a Member State cannot refuse to register a vehicle covered by a valid Community certificate unless it rules that it poses a serious road safety risk. Consequently, a possibility set out in national legislation to refuse registration, based on consideration of the environment, does not fulfil the conditions for exception prescribed in the Directive.

There is therefore no possibility (with the exception of the environmental guarantee in Article 95.5 of the EC Treaty) of prohibiting, by way of national legislation, type-approved vehicles containing mercury.

The Directive is incorporated into Swedish law by the Vehicle Ordinance (2002:925).

Directive on end-of-life vehicles

Directive 2000/53/EC on end-of life vehicles

The Directive has its legal basis in Article 175 of the EC Treaty. Article 3.2 of the Directive on end-of-life vehicles states that the Directive shall apply without prejudice to existing Community legislation and relative national legislation, in particular as regards safety standards, air emissions and noise controls and the protection of soil and water.

According to Article 4.2 a, Member States shall ensure that materials and components of vehicles put on the market after 1 July 2003 do not contain, for example, mercury other than in cases listed in an annex to the Directive. The annex states that mercury may be contained in lightbulbs and dashboard lighting.

The Directive is incorporated into Swedish law by Ordinance 2003:208 on bans on certain metals in cars.

⁴³ Ruling of the Court of Justice (Fifth Chamber) of 29 May 1997. Proceedings relating to administrative law that have been commenced by VAG Sverige AB. Request for a preliminary ruling: the Stockholm County Administrative Court – Sweden. Registration of vehicles – National certificate of exhaust emission approval – Conformity with Directive 70/156/EEC. Case C-329/95.

The Electronics Directive

*Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (The RoHS Directive)*⁴⁴

The RoHS Directive restricts the use of certain hazardous substances, including mercury, in electrical and electronic products. According to the RoHS Directive, Member States shall, as of 1 July 2006, ensure that new electrical and electronic products placed on the market do not contain certain substances, such as mercury. An annex to the Directive specifies exceptions from the rule, and certain use of mercury is therefore permitted. The exceptions refer mainly to light sources. The background of the Directive is the number of problems involved in the waste management of electrical and electronic products containing these hazardous substances. A restriction on the substances will probably result in easier waste management and greater possibilities for recycling material from product waste. This also contributes to the protection of health and the environment.

Article 2.1 of the RoHS Directive specifies the scope of application of the Directive by reference to Directive 2002/96/EC (the WEEE Directive) which regulates waste. The WEEE Directive specifies the categories of electrical and electronic equipment⁴⁵ and examples of such products as are included in the different categories of electrical and electronic products covered by the WEEE Directive and, therefore, also by the RoHS Directive.

RoHS shall be applied to the following products:

- Large and small household appliances
- IT and telecommunications equipment
- Consumer equipment
- Lighting equipment
- Electrical and electronic tools (with the exception of large-scale stationary industrial tools)
- Toys, leisure and sports equipment

⁴⁴ Electrical and electronic equipment is also covered by the proposal for a directive of the European Parliament and of the Council on establishing a framework for the setting of Eco-design requirements for energy using products and amending Council Directive 92/42/EEG). The proposal involves CE marking of energy using products and is a new-approach directive. Energy using products could therefore, in accordance with the proposal, be CE marked if they contain mercury (the RoHS Directive must, however, be taken into account). The EuP Directive takes protection of the natural environment into consideration and involves a harmonisation of the national regulations. The possibilities for prohibiting energy using products that contain mercury and are CE marked in accordance with the proposal are thus very limited.

⁴⁵ Article 2 of the RoHS Directive specifies what is meant by "electrical and electronic equipment" by referring to the WEEE Directive. It consists of large and small household appliances, IT and telecommunications equipment, consumer equipment, lighting equipment, electrical and electronic tools (with certain exceptions), toys, leisure and sports equipment and vending machines.

- Automatic dispensers

The RoHS Directive has not yet been incorporated into Swedish law. Member States shall bring into force the laws and other regulations necessary to comply with the RoHS Directive before 13 August 2004.

The RoHS Directive has its legal basis in Article 95 of the EC Treaty. Article 1 of the RoHS Directive prescribes that the purpose of the Directive is to approximate the laws of the Member States on the restrictions of the use of hazardous substances in electrical and electronic equipment and to contribute to the protection of human health and the environmentally sound recovery and disposal of waste electrical and electronic equipment. The purpose of the RoHS Directive is therefore harmonisation of the laws of the Member States, and it takes into consideration both the effects on the natural environment and on human health. This means that possibilities for Member States to introduce national regulations are very limited and consist only of the environmental guarantee.

Those categories of electric and electronic equipment covered by the WEEE Directive but not, at present, by the RoHS Directive, are not included in the area harmonised by the RoHS Directive⁴⁶. This means there is a theoretical possibility of national regularisation of the handling of mercury in these products.

An annex to the RoHS Directive lists exceptions from the ban on the use of mercury in new electrical and electronic equipment. One of the exceptions involves “mercury in other lamps not specifically mentioned in this Annex”. The purpose of the exception is probably not the harmonisation of the laws of the Member States in such a way that use of mercury in these lamps is completely unrestricted. On the contrary, the reason for the exception is that there at present is no basis for regulating these lamps. This means in theory that it would be possible to introduce a national ban on mercury in these lamps. It is probably not possible, however, to proceed in this way since there are rules regarding review in Article 6 of the RoHS Directive. There might therefore be a practical limitation against introducing national rules since the Commission would probably prevent national regulation by referring to the rules regarding review.

The rules regarding review mean, among others, that before 13 February 2005 the Commission shall review the measures provided for in the Directive and take into account new scientific evidence. For example, medical devices and monitoring and control instruments may be included in the area of application, and additional products for which satisfactory alternatives do not yet exist may be included in the annex of exceptions to the Directive.

⁴⁶ This involves medical devices (with the exception of all implanted and infected products) and monitoring and control instruments. The medical devices are regulated in the Medical Devices Directive.

The Export and Import Regulation

Regulation (EC) No 304/2003 concerning the export and import of dangerous chemicals

The Regulation implements the Rotterdam Convention on the prior informed consent (PIC) procedure. It contains rules on information procedure on the export/import of specified chemicals to third countries outside the EU and rules on how decisions from the import country shall be regarded. Additionally, the Regulation contains certain rules on direct export bans (Annex 5), which partly apply to such persistent organic pollutants (POPs) as are listed in the Stockholm Convention, and partly to cosmetic soaps containing mercury.

The Regulation lists requirements regarding the export and import of, for example, mercury compounds.⁴⁷ The Regulation only covers import and export to and from the EU area and not to and from each individual Member State. The Regulation therefore occupies a place apart compared to other regulations accounted for above, both because it is a regulation and not a directive, and because it regulates the relationship between the EU and third countries and not the situation within the EU. This means that the Regulation, with the exception of cosmetic soaps containing mercury, which may not be exported, does not have any significance with regard to the introduction of national regulations on a ban on mercury. Furthermore, the ban on the export of cosmetic soaps containing mercury doesn't involve a restriction on the possibilities of introducing national regulations, since the control laid down in the Regulation involves a ban.

The Packaging Directive

Directive 94/62/EC on packaging and packaging waste

According to Article 1 of the Packaging Directive, the objective of the Directive is to harmonise national measures concerning the management of packaging and packaging waste in order to ensure a high level of environmental protection and to ensure the functioning of the internal market and to avoid obstacles to trade and distortion and restriction of competition within the Community. Article 18 states that Member States shall not impede the placing on the market of packaging which satisfies the provisions of the Directive. The Directive has its legal basis in Article 95 of the EC Treaty and its objective is therefore a harmonisation of the national regulations. The Directive includes all packaging placed on the market within the Community.

The Directive is only partly formulated in accordance with the New Approach. The Packaging Directive lists essential requirements regarding the composition of packaging, requirements which are supplemented by standards (Article 9 and Annex 2). In the Packaging Directive, however, the presence of hazardous substances in packaging has been exempted from the essential requirements (with the exception of

⁴⁷ For example, cosmetic soap containing mercury may not be exported, see further Annex 5 of the Regulation.

certain aspects of waste management). The content of particularly hazardous substances (e.g. mercury) is regulated in a separate article (Article 11). Consequently, in this case it has not been considered appropriate to apply standards, choosing instead to specifically regulate the use of certain chemicals in the Directive. It is not possible to introduce stricter national rules since the purpose of the rules is harmonisation, and environmental protection has been taken into consideration.

The Directive has been incorporated into Swedish law by Ordinance 1997:185 on manufacturers' responsibility for packaging and Ordinance 1998:944 on prohibitions etc. in certain cases in connection with the handling, import and export of chemical products.

The Cosmetics Directive

Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products

The legal basis of the Cosmetics Directive is Article 94 of the EC Treaty, which deals with directives on the approximation of such laws and other regulations in the Member States as have a direct influence on the establishment and functioning of the common market. The Cosmetics Directive is not a new-approach directive. Article 7 of the Cosmetics Directive states that Member States may not, for reasons related to the requirements laid down in the Directive and its Annexes, refuse, prohibit or restrict the marketing of any cosmetic products which comply with the requirements of the Directive and its annexes. The purpose of the Directive is therefore a harmonisation of the national laws. Effects on the natural environment are not, however, taken into account and, stricter national rules can thus be introduced on these grounds.

The Cosmetics Directive states that cosmetic products put on the market within the Community must not be liable to cause damage to human health when they are applied under normal conditions of use. The Member States shall prohibit the placing on the market of cosmetic products containing substances listed in an annex to the Directive. The annex lists, for example, mercury and its compounds. The Directive includes, however, exceptions from the provision. The exceptions mean that certain preservatives are permitted. Phenylmercuric salts and thiomersal with a maximum mercury concentration of 0.007% are permitted. They may, however, only be used for eye makeup and eye makeup removal products.

The Cosmetics Directive has been incorporated into Swedish law by Ordinance (1993:1283) on cosmetic and hygiene products and regulations of the Medical Products Agency⁴⁸.

⁴⁸ LVFS 1993:2, amended and reprinted by LVFS 2003:5

The Toy Safety Directive

Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys

The Toy Safety Directive is a new-approach directive with its legal basis in Article 95 of the EC Treaty. According to Article 4 of the Toy Safety Directive, Member States shall not impede the placing on the market of toys which satisfy the provisions of this Directive. The purpose of the regulation is, therefore, harmonisation of national rules.

Those toys satisfying the requirements laid down within the scope of the Directive are CE marked. Annex 2 lists essential safety requirements for toys. According to the Annex, with regard to chemical properties, for the protection of children's health, bioavailability resulting from the use of toys must not, as an objective, exceed certain levels per day.⁴⁹

Toys must not contain hazardous substances or preparations with the meaning of Directives (67/548/EEC) and (99/45/EC⁵⁰)⁵¹ in amounts which may harm the health of children using them. At all events it is strictly forbidden to include, in a toy, hazardous substances or preparations if they are intended to be used as such while the toy is being used. However, where a limited number of substances or preparations are essential to the functioning of certain toys, e.g. materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, they are permitted up to a maximum concentration level to be defined for each substance or preparation by mandate to the European Committee for Standardisation (CEN).

The Directive harmonises the laws and other regulations of the Member States as regards health and safety requirements for toys. Therefore there is probably a possibility of introducing a national ban on the handling of mercury, by referring to protection of the natural environment. Toys are, however, also regulated within the scope of the RoHS Directive, which involves a restriction on the possibility of introducing national rules.

The Directive has been incorporated into Swedish law by Ordinance 1993:97 on the safety of toys and by regulations of the Swedish Consumer Agency.⁵²

⁴⁹ 0.5 µg for mercury

⁵⁰ In the Toy Safety Directive reference is made to Directive 88/379/EEC which was replaced by Directive 99/45/EEC

⁵¹ The substance and preparation directives list, for example, mercury, mercurous chloride [dimercury dichloride], mercury fulminate, organic mercury compounds and inorganic mercury compounds (with certain exceptions) and mercury oxycyanide (see in addition p 346 in KIFS 2001:3 directives on change in the National Chemicals Inspectorate's regulations (1994:12) on classification and labelling of chemical products)

⁵² KOVFS 1993:9

The Medicinal Products Directive and Regulation

Regulation (EEC) No 2309/93 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, directive 2001/82/EC on the Community code relating to veterinary medicinal products and directive 2001/83/EC on the Community code relating to medicinal products for human use

The legal basis of the Regulation is Article 235 of the EC Treaty and the legal basis of the Directive is Article 95 of the EC Treaty and this means that both veterinary medicinal products and medicinal products for human use must be authorised before being placed on the market.

The Directive has been incorporated into Swedish law by the Medicinal Products Act (1992:859).

A medicinal product can be authorised in different ways. It can either be authorised centrally by the Commission after a recommendation from the central medicinal products authority in London⁵³ or in each individual Member State⁵⁴. If the medicinal product is granted authorisation centrally, it has authorisation in the whole of the EU. The other alternative is mutual recognition. This means that the medicinal product is granted authorisation in one Member State and that it subsequently, after application, is granted authorisation in the other EU countries in accordance with a simplified procedure. If the product is not intended for any other country, the authorisation is thus purely national. It is not possible to apply for national authorisation if the product is authorised in another EU country.

There is no general ban on the use of products containing mercury, these being accepted if the products are deemed to be suited to their purpose. Mercury is found in certain medicinal products in the form of the preservative thiomersal or phenylmercuric nitrate and as an active substance in homeopathic remedies.

Legislative provisions regarding authorisation of medicinal products have recently been changed. The changes have not yet been published in the European Union's Official Journal.

A medicinal product has previously been authorised on the basis of an assessment of effects on the health of Man and of animals without taking into account the effects on the natural environment. The new regulations mean that, with regard to veterinary medicinal products, environmental effects are taken into account when

⁵³ Council Regulation (EEC) No. 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.

⁵⁴ The European Parliament's and the Council's Directive 2001/82/EC of 6 November 2001 on the Community code relating to medicinal products for human use

assessing the product's acceptability and that, with regard to medicinal products for human use, a review of environmental effects will be carried out but that the result will not affect the assessment of whether or not a medicinal product will be granted authorisation or not.

The purpose of the Regulation and the Directives is harmonisation of the laws of the Member States but they primarily take into consideration the effects which medicinal products have on the human and animal health. The Directive on veterinary medicinal products, however, takes into account the effects on the natural environment after the review and the possibility of introducing a national ban on mercury is therefore limited to the possibilities in the environmental guarantee. After review, however, the Directive on medicinal products for human use only takes the effects on human health into account and not effects on the natural environment, even although an environmental impact assessment is to be made. In the Directive's preamble it says "the environmental impact should be assessed and, on a case-by-case basis, specific arrangements to limit it should be envisaged. In any event this impact should not constitute a criterion for refusal of marketing authorisation". When authorising a medicinal product for human use, effects on the natural environment shall not be taken into account after review either. It could therefore be possible to introduce a national ban on mercury, taking into account that effects on the natural environment are not covered by the area which is deemed to be harmonised.

The Medical Products Agency considers that the text in the preamble and the Directive mean that the Member States may not impose requirements on medicinal products for human use with regard to effects on the environment and that this would make it impossible to introduce national rules banning mercury in medicinal products (Lindström and Welin, personal communication).

The Medical Devices Directive

Directive 93/42/EEC concerning medical devices

The Directive has its legal basis in Article 95 of the EC Treaty and is a new-approach directive. This means that the area is harmonised. This is expressed, inter alia, in Article 4 of the Directive where it is expressly stated that Member States may not prevent the products being placed on the market or being put into service if they have been CE marked in accordance with the provisions of the Directive.

The rules and requirements in the Directive have been incorporated into Swedish law by the act (1993:584) on medical devices, Ordinance 1993:876 on medical devices and the regulations which, under the provisions of the ordinance, have been issued by the Medical Products Agency and the National Board of Health and Welfare⁵⁵.

⁵⁵ LVFS 2001:5, LVFS 2001:6, LVFS 2001:8, LVFS 2002:2, LVFS 2003:3 and SOSFS 2001:12.

All medical devices not specially adapted or intended for clinical examination shall bear the CE mark when they are placed on the market. Medical devices are divided into four classes (Classes I, IIa, IIb and III). The classification is based on the risks to which the human body can be subjected on account of the product's construction, method of production or use.

In order to bear the CE mark, a medical device shall be suitable for its use. The product is suitable if, during normal use for its purpose, it achieves what the manufacturer has intended and it satisfies strict requirements regarding protection of life, personal safety and health of patients, users and others. Effects on the natural environment during production and use of medical devices are not taken into account when making the decision about CE marking.⁵⁶

Responsibility for ensuring that the product complies with the product requirements is borne by the manufacturer who also affixes the CE mark to the product. With regard to medical devices in Class I, the manufacturer himself may assess whether the product fulfils the applicable requirements. For products in Classes IIa, IIb or III, the assessment must be carried out in cooperation with a registered body.

There are a number of medical devices containing mercury, for example clinical thermometers, sphygmomanometers and dental materials.

The Medical Devices Directive is a new-approach directive and involves harmonisation of medical devices. The possibilities for Sweden to prevent CE marked medical devices being placed on the market or taken into service within the country are therefore limited. Effects on the natural environment during production and use of medical devices are not taken into account when deciding on CE marking. A Member State could therefore introduce a national ban on handling mercury by referring to the fact that effects on the natural environment are not regulated by the Directive⁵⁷.

⁵⁶ It appears from Article 2 of the Medical Devices Directive that only health and safety are taken into account. Cf PM no. 4/96, the National Chemicals Inspectorate, *Avveckling av amalgam inom tandvården, rapport av ett regeringsuppdrag* (Phasing out of Amalgam within Dental Care, a report of a commission from the government), page 22

⁵⁷ Cf. Denmark's introduction of a ban on amalgam for use other than "tandfyldning af blivende kindtænder, hvor der er slid på fyldningen" (Bekendtgørelse om forbud mod import, slag og eksport af kviksølv og kviksølvholdige produkter – BEK nr 627 af 01/07/2003)

Annex 5

Questions to stakeholders concerning the handling of mercury

Questions on the handling of mercury

Company/Organisation.....
Contact.....
Phone..... E-mail.....

Our company/organisation considers the information provided by us as confidential

When answering the questions, please:

- consider both positive and negatives aspects and consequences,
- indicate whether a private person, company, trade and industry or society at large is concerned and whether it is on a national, regional or international level, respectively,
- enclose data to support or clarify your answer,
- provide detailed answers when possible,
- note that in the case of use areas that have already been considered by KemI, primarily developments and data for 1998 and onwards are of interest.

Please consult the guide to each question (last page) in order to ensure as correct an assessment of needs and consequences as possible.

1 a. What amounts of mercury and mercury compounds are handled by your company/organisation?
Please see the guide on the last page.

1 b. In which applications do you handle mercury and mercury compounds in any form?
Please see the guide on the last page.

2. Are activities going on to phase out the use of mercury in your company/organisation or within your sector?

Yes, activities are going on.

No activities are going on.

If yes:

Describe these activities (Please see the guide on the last page).

3. Do you have any experience or knowledge of alternative chemicals, materials or techniques to using and handling mercury?

Yes, we have experience and knowledge of alternatives to mercury.

No, we have no experience and knowledge of alternatives to mercury.

If yes:

Please describe (see the guide on the last page).

4a. Do you apply any norms, test methods or standards governing the use of mercury?

Yes

No

If yes:

4b. What are they and in what way do they govern and constrain your work?
Please describe (see the guide on the last page).

4c. In what way do they have an impact on a possible changeover to alternatives to mercury?

Please describe (see the guide on the last page).

5. Is there a demand for alternatives to mercury?

Yes

No

If yes:

Please describe the present situation (see the guide on the last page).

6. What impact would a ban of mercury have on your company/organisation?
(If handling is already banned, please describe in what way a refusal of a future application for exemption would effect your company/organisation)

Please describe the consequences (see the guide on the last page).

7. Do you consider it would be necessary to obtain an exemption from a ban?

Yes

No

If yes:

Describe why (see the guide on the last page).

8. Additional information you would like to provide:

Guide to questions on the use of mercury

Question 1

If you do not wish to reveal a piece of information for secrecy reasons, please indicate this.

State the amount (indicate if it is an estimation) and, if possible, state the amount per use area, number of measuring instruments, etc. State methods, kind of instruments etc. for methods of analysis. Estimate number of purchases a year and interval for ongoing use, respectively. State also if the handling refers to an added amount of mercury or if it concerns existing equipment, etc.

Question 2

Voluntary activities such as phase-out, substitution, information and other risk-limiting measures should be included. Activities initiated or conducted nationally or internationally (within EU or outside) by single companies or mutually within the sector.

Question 3

Are there any alternatives available on the market? If so, what alternative chemicals, materials, or techniques are there? How do they meet the requirements made from the viewpoints of technical and safety properties? What information/data is available on these alternatives with regard to environmental and health aspects, safety, quality, durability, etc? Is any research and development going on to find alternatives? Is there any remaining development work to adapt your operations to a ban? Is there a need for a limited transitional period for a changeover to alternatives? How long a period would your company/organisation or sector need to phase out the use of mercury?

Question 4

For example, international standards could indicate that mercury should be used in certain analyses, in measuring instruments or in other equipment. EC directives could also state that mercury should be included in certain equipment.

Question 5

Does the supply meet the demand? How are the costs of the alternatives compared with mercury? Are costs of alternatives higher or have they decreased concurrently with an increased demand?

Question 6

Which consequences would a ban entail from the viewpoint of business economy and its costs and revenues, administration such as applicability, time aspects, personnel costs, other costs or resource loads, competition conditions, education requirements, research and development, environmental and health aspects, safety and quality aspects, etc? How important or how extensive are these effects and consequences? What would the impact on business and trade (economy) and the society be? How would your company's/institution's competitive conditions change if a national ban was implemented compared with a corresponding ban initiated within the EU?

Question 7

For what use do you consider an exemption necessary? What is the reason (socio-economic aspects, lack of available alternatives, technical reasons, customer requirements, etc.)? Please give examples supporting your answer. Proposals for time-limited exemptions? How large an amount of mercury would that exemption represent?

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