

National plan of Dental amalgam
phase out
Swedish experiences

PM 3/19

KEMI

Swedish Chemicals Agency

The Swedish Chemicals Agency is supervisory authority under the Government. We work in Sweden, the EU and internationally to develop legislation and other incentives to promote good health and improved environment. We monitor compliance of applicable rules on chemical products, pesticides and substances in articles and carry out inspections. We review and authorise pesticides before they can be used. Our environmental quality objective is A Non-toxic Environment.

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Preface

EU Member States shall establish a national plan with the measures intended to implement the phase out the use of dental amalgam by 1 July 2019. The Member States shall publish their national plans on the Internet and send them to the Commission within one month of adoption. This is the result of additional tasks for the Swedish Chemicals Agency, in accordance with instructions (SFS 2018:1988) from the government.

This is in accordance with Article 10.3 in Regulation (EU) 2017/852 on mercury, and repealing Regulation (EC) No 1102/2008 and due to amendments in Regulation (2008:245) on chemical products and biotechnical organisms.

Sweden has already phased out dental amalgam and therefore the national plan does not include new measures but sets out the approach for the phase out.

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Summary

The Swedish Chemicals Agency describe, in this memorandum, the approach of the phase out of dental amalgam in Sweden. All EU Member States are requested to publish a national plan with measures to phase out dental amalgam. Sweden has a general mercury ban since 2009 and has already phased out dental amalgam. This national plan therefore sets out the approach of the phase out.

Amalgam has been used as a tooth-filling material since the 1800s. Precautionary measures against the use of mercury were initiated in Sweden already back in the 1960s due to the manifestation of environmental damage. In 1969 the Swedish Environmental Protection Act was adopted. Co-benefits of implementing this act was reduced emissions of pollutants such as mercury.

In 1991, a regulation was introduced which banned certain products (electrical and electronic measuring instruments) containing mercury from being manufactured or sold. Also in 1991, the National Board of Health and Welfare proposed a phasing-out process to cease the use of amalgam in dentistry for children and young people from 1995 and cease the use entirely by 1997. An investigation established that this was not possible by 1997. However, the use of amalgam could be reduced further. To make amalgam more cost-neutral against other filling materials, the Swedish Parliament decided in 1999 not to give financial support for amalgam fillings via the national dental insurance any longer.

These measures resulted in substantial reductions in the amount of mercury used in products. Between 1992 and 2003, approximately 95 per cent of sold amounts of mercury was phased out.

In 2009, a general ban on mercury came into force that better corresponded with the Swedish environmental quality objective for “a non-toxic environment”.

In Sweden, alternatives such as composites, ceramics and metal alloys have successfully replaced dental amalgam. In 2017, dental amalgam was used once for restoration. In 2018, there were no restorations with dental amalgam.

The reasons behind this success are access to mercury-free alternatives, as well as a demand for them, and a high awareness of the risks with mercury for environment and health both among patients and dentists. Initially, allergies to composite materials was a larger problem than expected, due to lack of product information. The Swedish Chemicals Agency carried out an inspection project to increase the awareness and ensure manufacturers and importers improved the product information and safety data sheets.

Even if dental amalgam is not used, existing dental amalgam fillings in Swedish adult’s teeth will be a source of mercury release for decades.

In order to minimize emissions of mercury Praktikertjänst (a Swedish group in private dental and health care) has initiated an EU funded project. The project has developed recommendations for routines aimed at minimizing the release of mercury from dental care clinics in Sweden. Another part of the project is to develop more effective methods for decontamination.

Sammanfattning

Kemikalieinspektionen beskriver i detta PM hur utfasningen av amalgam i tandfyllningar har gått till i Sverige. Samtliga EU:s medlemsländer har ombetts redogöra och publicera en handlingsplan med åtgärder för utfasning av tandamalgam. Sverige har sedan tio år tillbaka ett generellt förbud mot kvicksilver och har redan fasat ut amalgam. Därför är handlingsplanen en historisk redogörelse över tillvägagångssättet.

Amalgam har använts som tandfyllningsmaterial sedan 1800-talet. Försiktighetsåtgärder mot användningen av amalgam initierades i Sverige redan på 1960-talet efter att miljöskador påvisats. 1969 antogs Miljöskyddslagen (1969:387) och positiva sidoeffekter av lagen var minskade utsläpp av föroreningar som kvicksilver.

1991 infördes en förordning som förbjöd försäljning av vissa produkter (elektriska och elektroniska mätinstrument) som innehöll kvicksilver.

1991 föreslog Socialstyrelsen en utfasningsprocess där amalgam skulle upphöra att användas inom tandvården för barn och unga från 1995, för att sedan helt upphöra 1997. Det fastslogs dock i en utredning att det inte var möjligt till 1997. Däremot kunde amalgamanvändningen minskas ytterligare. För att göra amalgam mer kostnadsneutralt mot andra fyllnadsmaterial beslutade riksdagen 1999 att inte längre ge ekonomiskt stöd för amalgamfyllningar via tandvårdsförsäkringen.

Åtgärderna gav betydande minskningar i kvicksilveranvändningen i produkter. Närmare 95 procent av sålda mängder kvicksilver fasades ut mellan åren 1992 och 2003.

Ett generellt förbud mot kvicksilver trädde i kraft 2009 vilket bättre överensstämde med det svenska miljö kvalitetsmålet för Giftfri miljö.

I Sverige har tandamalgam lyckosamt ersatts av alternativ som bland annat komposit, keramer cement eller olika metallegeringar. 2017 användes tandamalgam vid en lagning och 2018 användes det inte alls.

Anledningarna till framgångarna är tillgång till kvicksilverfria alternativ samt efterfrågan och en hög medvetenhet om riskerna med kvicksilver för miljö och hälsa både bland patienter och tandläkare. Initialt var allergier mot kompositmaterialen ett större problem än väntat på grund av bristande produktinformation. Kemikalieinspektionen genomförde ett inspektionsprojekt för att öka medvetenheten och säkerställa att tillverkare och importörer förbättrade produktinformation och säkerhetsdatablad.

Trots att tandamalgam idag inte används kommer befintliga tandamalgamfyllningar hos vuxna svenskar vara en källa till kvicksilverutsläpp i decennier framöver.

För att minimera kvicksilverutsläpp har Praktikertjänst (företag inom privat tand- och sjukvård) initierat ett EU-finansierat projekt. Projektet har utvecklat rekommendationer för rutiner som syftar till att minimera kvicksilverutsläpp från tandvårdskliniker i Sverige. En annan del i projektet är att utveckla mer effektiva metoder för sanering.

1 Scope of the assignment

The EU-Commission has requested all EU Member States to establish national plans with measures to phase out dental amalgam. This is in accordance with newly introduced requirements in EU regulation (2017/852) on mercury.

By 1 July 2019, the national plan shall be publicly available on the internet and transmitted to the EU-Commission within one month of adoption.

The Swedish Chemicals Agency produced the national plan in accordance with instructions (SFS 2018:1988) from the government and due to amendments in Regulation (2008:245) on chemical products and biotechnical organisms.

Sweden phased out dental amalgam several years ago and the plan therefore sets out the approach of the phase out.

2 Background

Mercury causes severe health and environmental damage, which is well-known in Sweden. Measures against the use of mercury were initiated in Sweden already back in the 1960s. Bans against the use of mercury in seed dressing were introduced after injuries in e.g. birds had been demonstrated. In addition, rather early in the process recommendations against eating too much fish were introduced. Such food restrictions are still valid (National Food Agency, 2019).

2.1 Introduction of Swedish Environmental Protection Act

In 1969 the Swedish Environmental Protection Act was adopted. Requirements were primarily aimed at reducing sulphur dioxide, nitrogen oxides and particulate matter but co-benefits of implementing these measures were reduced emissions of other pollutants, such as mercury, lead, cadmium and dioxins. Mercury emissions from Swedish point sources have decreased from about 5.5 tonnes in 1985 to about 0.5 tonnes in 2012 (The Swedish EPA and the Swedish Chemicals Agency, 2014).

2.2 General ban of mercury

During the early 1990s, product-specific bans were introduced in Sweden. In 1991, a regulation was introduced which banned certain products (electrical and electronic measuring instruments) containing mercury from being manufactured or sold. Dental amalgam was not regulated at this point but the overall goal of a phase-out of mercury also included dental amalgam, as a precautionary measure to minimise the exposure to metal mercury vapour. This led to a voluntary reduction of new amalgam fillings in children's teeth from 30 to 1.5% between 1991 and 1995. The use in adult's teeth decreased from 32 to 15%.

These measures resulted in substantial reductions in the amount of mercury being used in products. Between 1992 and 2003, approximately 95 per cent of sold amounts of mercury was phased out. However, areas of use remained – and new ones could arise – which were not covered by the legislation.

It was recognised that a general ban would better correspond with the Swedish environmental quality objective for “a non-toxic environment”. On 1 June 2009, a general ban on mercury came into force. This general ban states that:

- Mercury, or mercury compounds or preparations including dental amalgam, must not be placed on the Swedish market; nor is it permitted to use mercury in Sweden or to commercially export mercury from Sweden.
- Mercury-containing goods must not be placed on the Swedish market or commercially exported from Sweden.
- Mercury-containing products already in use prior to the ban may still be used but must not be placed on the market or exported. It is not permitted to refill these products with new mercury.

A number of time-limited exemptions have been granted by the Swedish Chemicals Agency. Uses where harmonised European Union legislation applies, such as electrical and electronic equipment and batteries, are also exempted from the Swedish ban.

3 Dental amalgam phase out

In Sweden, dental amalgam has successfully been replaced by alternatives such as composites, ceramics, glass ionomer cement and cast metal (mainly cobalt-chromium alloys, titanium and gold alloys). In 2017 dental amalgam was used once for restoration. In 2018 there were no restorations with dental amalgam¹.

The reasons behind this success are access to mercury-free alternatives, as well as a demand for them, and a high awareness of the risks with mercury for environment and health both among patients and dentists. Initially, allergies to composite materials was a larger problem than expected, due to lack of product information. The Swedish Chemicals Agency² carried out an inspection project to increase the awareness and ensure manufacturers and importers improved the product information and safety data sheets (The Swedish Chemicals Agency, 1997).

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 at the time was amalgam (The Swedish Chemicals Agency, 2004).

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 (SOU, 2003:53).

As a stage in the phase-out, an agreement was made between the state and the county councils in 1995 to phase out dental amalgam from children's dentistry. An investigation made by The Swedish Chemicals Agency³, in consultation with the National Board of Health and Welfare, established that total phasing out of amalgam by 1997 was not possible but that its use could

¹ Prepared by Wood Environment & Infrastructure Solutions UK Ltd for the European Commission (2019). Questionnaire health aspects. Assessment of the feasibility of phasing out dental amalgam.

² Named the Swedish Chemicals Inspectorate at that time.

³ Named the Swedish Chemicals Inspectorate at that time.

be reduced further. The investigation showed that despite the 1995 agreement amalgam was still used for fillings even though alternatives were available and, remarkably, often for the repair of children's teeth.

To make amalgam more cost-neutral against other filling materials, the Swedish Parliament decided in 1999 that no financial support should be given for amalgam fillings via the national dental insurance. At that time, it was concluded that there were no immediate obstacles against these changes, alternatives with less environmental impact as well as being medically reliable were available. The fee for amalgam fillings were lower at the time, and taking the financial support away for them made the choice between amalgam and alternatives cost neutral for the patient.

Dental health in Sweden is in general good. The use of amalgam reduced successively during the 1990s and the phase-out of dental amalgam was nearly complete before the general ban on mercury was in place 2009.

Even if dental amalgam is not used, existing dental amalgam fillings in Swedish adult's teeth will be a source of mercury release for decades. Amalgam is the single largest source of mercury contamination of sewage sludge in Sweden. Crematoria are a significant contributor to atmospheric mercury emissions. An estimated 74 % of the adult Swedish population has amalgam fillings, and the amount of mercury in the teeth of people in Sweden is estimated to about 40 metric tons. Since 1985 all dental clinics have amalgam separators installed following a voluntary agreement in 1979. All large crematoria (about 90 % of cremations) are equipped with mercury control techniques using activated carbon.

Table 1. Important years in the phase out of mercury and amalgam in Sweden

1969	Adoption of the Swedish Environmental Protection Act
1979	Introduction of amalgam separators (voluntary agreement with dentists associations, requiring all dental clinics to be equipped with amalgam separators)
1991	Ban for mercury in measuring devices
1993	Phase out of dental amalgam use in temporary teeth (agreement between the government and the county council associations)
1995	Phase out of dental amalgam from children and adolescent dental care (agreement between the government and the county council associations)
1997	Objective to phase out amalgam also in adult dental care
1999	Decision to withdraw fringes for dental amalgam (cost neutrality)
2009	General Mercury ban, including dental amalgam, with some exemptions
2018	General exemptions for use of dental amalgam withdrawn (possibility to apply for onetime/short term exception will remain)

3.1 EU-project on minimizing emissions of dental amalgam

In order to minimize emissions of mercury Praktikertjänst (a Swedish group in private dental and health care) has initiated a project with financial support from LIFE - EU's financial instrument supporting environmental, nature conservation and climate action projects throughout the EU. The project's main purpose is to minimize emissions of mercury from dental clinics in Sweden and eventually the rest of the EU. Dental care clinics carry a great responsibility for the reduction of amalgam emissions since the release of mercury is a threat to the environment.

The project has developed recommendations for routines aimed at minimizing the release of mercury from dental care clinics in Sweden. Hopefully the guidelines will inspire and be a support in other countries' work on developing recommendations. Another part of the project is to develop more effective methods for decontamination. Praktikertjänst has within the framework of the project so far collected 16 kg of pure mercury after decontaminating 60 dental facilities. Read more about the project at www.hg-rid.eu/en.

Swedish Regulations on mercury

- Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944), 8-11 §§. http://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/forordning-1998944-om-forbud-mm-i-vissa-fall_sfs-1998-944#Kvicksilver (in Swedish)
- Brief facts about the general mercury ban: <https://www.kemi.se/en/rules-and-regulations/additional-eu-rules/mercury/brief-facts-about-mercury>
- [The Swedish Chemicals Agency's Chemical Products and Biotechnical Organisms Regulations \(KIFS 2017:7\)](#) which regulates the exemptions of the general ban. <https://www.kemi.se/lagar-och-regler/kifs--kemikalieinspektionens-foreskrifter/kifs-20177> (in Swedish)

4 Bibliography

National Food Agency, S., 2019. *Kvicksilver*. [Online]

Available at: <https://www.livsmedelsverket.se/livsmedel-och-innehall/oonskade-amnen/metaller1/kvicksilver>

[Använd 21 May 2019].

SOU, 2003:53. *Dentala material och hälsa*, Stockholm: The Swedish Government.

The Swedish Chemicals Agency, 1997. *Ihålig produktinformation om tandfyllning. Ett inspektionsprojekt. Rapport 8/97*, Solna: The Swedish Chemicals Agency.

The Swedish Chemicals Agency, 2004. *Mercury – investigation of a general ban. KemI report no 4/04*, Solna: The Swedish Chemicals Agency.

The Swedish EPA and the Swedish Chemicals Agency, 2014. *Mercury management in Sweden*, Stockholm: The Swedish Environmental Agency.

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