

#### Plan for the abolition of dental amalgam by 2030

National plan required by an EU regulation

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#### **Abstract**

Mercury is a contaminant, one of the leading sources of which in Europe is dental amalgam. The aim of the Minamata Convention's Regulation on Mercury (EU 2017/852), which was implemented in the EU, is to minimise and, where feasible, entirely eliminate global anthropogenic mercury releases by the year 2030. The Regulation is to be regarded as directly applicable legislation in Finland. Each EU country must publish a national plan for the abolition of dental amalgam and the collection of accumulated dental amalgam waste by 1 July 2019.

In Finland, the use of dental amalgam has decreased from year to year to a level where it only constitutes clearly less than 1% of all dental fillings produced. Even though the majority of Finnish dentists have abandoned dental amalgam, it still has a user base. In fact, there are some indications that fillings made from amalgam would appear to be more durable and affordable than other filling materials. Many Finns still have old amalgam fillings in their teeth due to their longevity. In Finland, the collection of waste generated from the removal of amalgam fillings has been handled appropriately, but more detailed instructions are required for the recycling of secondary waste that has been contaminated with mercury.

Although very little amalgam is used in Finland, its full abolition requires comprehensive cooperation with regard to material development, communications and education, among other things. This document presents the national action plan for abolishing amalgam in Finland by the year 2030.

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#### Tiivistelmä

Elohopea on ympäristömyrkky, jonka suurimpia lähteitä Euroopassa on hammasamalgaami. EU:ssa toimeenpannun Minamatan yleissopimuksen niin sanotun elohopea-asetuksen (eu 2017/852) tavoitteena on minimoida ja mahdollisuuksien mukaan poistaa kokonaan ihmisen aiheuttamat maailmanlaajuiset elohopeapäästöt vuoteen 2030 mennessä. Asetus on sellaisenaan sovellettavaa lainsäädäntöä Suomessa. Jokaisen EU maan tulee julkaista kansallinen suunnitelma hammasamalgaamista luopumiseksi ja siitä kertyneiden jätteiden keräämiseksi 1.7.2019 mennessä.

Suomessa hammasamalgaamin käyttö on vähentynyt vuosi vuodelta niin, että sitä tällä hetkellä käytetään vain selvästi alle yhdessä prosentissa kaikista valmistettavista hammastäytteistä. Vaikka suurin osa suomalaista hammaslääkäreistä ei amalgaamia käytä, on sille olemassa edelleen oma käyttäjäkuntansa. Amalgaamilla onkin joitain indikaatioita, joissa siitä valmistetut täytteet vaikuttavat olevan muita täytemateriaaleja kestävämpiä ja edullisempia. Vanhoja amalgaamitäytteitä on suomalaisten hampaissa vielä runsaasti niiden pitkäikäisyyden vuoksi. Amalgaamitäytteiden purkamisesta syntyvän jätteen keräys on Suomessa hoidettu asianmukaisesti, mutta elohopealla kontaminoituneen sekundäärijätteen kierrätys vaatii vielä tarkempaa ohjeistusta.

Vaikka amalgaamin käyttö on Suomessa vähäistä, siitä kokonaan luopuminen vaatii monitahoista yhteistyötä muun muassa materiaalikehityksessä, viestinnässä ja koulutuksessa. Tässä dokumentissa esitetään kansallinen toimintasuunnitelma amalgaamista luopumiseksi Suomessa vuoteen 2030 mennessä.

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#### Referat

Den största källan i Europa för kvicksilver, som är ett miljögift, är tandamalgam. Målet med Minamatakonventionens så kallade kvicksilverförordning (EU 2017/852) som genomfördes i EU är att minimera och, när så är möjligt, slutligen helt undanröja de globala antropogena kvicksilverutsläppen till 2030. Förordningen utgör direkt tillämplig lagstiftning i Finland. Varje EU-land ska upprätta en handlingsplan för att fasa ut användningen av tandamalgam senast 1.7.2019.

I Finland har användningen av tandamalgam minskat år för år så att amalgamet för närvarande bara används i klart under en procent av alla tandfyllningar som tillverkas. Även om största delen av finländska tandläkare inte använder amalgam finns det fortfarande tandläkare som gör det. Det finns vissa indikationer att fyllningar som tillverkats av amalgam skulle vara hållbarare och billigare än andra fyllningar. Eftersom amalgamfyllningar är hållbara finns det fortfarande en stor mängd gamla amalgamfyllningar i finländarnas tänder. I Finland har avfall som uppstår från att amalgamfyllning avlägsnas skötts på behörigt sätt, men att återvinna kontaminerat sekundäravfall kräver fortfarande noggrannare instruktioner.

Trots att användning av amalgam är begränsad i Finland krävs samarbete med flera sektorer, bland annat samarbete med materialutveckling, kommunikation och utbildning för att helt avskaffa användningen. I detta dokument föreslås en nationell handlingsplan för att fasa ut användningen av amalgam i Finland till 2030.

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#### TO THE READER

The Minamata Convention on Mercury, which was agreed up under the auspice of the United Nations Environment Programme (UNEP), has been implemented in the EU with Regulation (EU) 2017/852 of the European Parliament and of the Council on mercury. The Minamata Convention is an international framework for cooperation and measures that will control and restrict the use of mercury and its compounds as well as mercury emissions and leaks into the air, waters and soil. The objective of the Convention is, where possible, to entirely eliminate human-caused worldwide mercury emissions. All EU Member States have committed to including the Convention as part of their national legislation and to implement it.

Preparation of dental amalgam fillings is one of the areas in which mercury is applied in the largest quantities in the EU and a significant source of environmental toxins. For this reason, its use should be phased-out. Every Member State must publish their national plan for this by 1 July 2019. It is the responsibility of the Ministry of Social Affairs and Health to draft Finland's plan on measures for ending the use of dental amalgam. This publication maps out the current use of dental amalgam in Finland and presents the national plan for phasing out its use by 2030.

Merja Auero and Ulla Harjunmaa June 2019

#### 1 Introduction

Mercury is an environmental toxin, which is enriched in the food chain and ends up in human bodies via food and water. Exposure to mercury poses a serious risk to a person's health. Although the majority of mercury emissions come from industry dental amalgam accounts for a significant share of mercury's environmental burden. The use of dental amalgam accounts for 24 per cent of all mercury use in the EU (Mudgal et al. 2012). The mercury contained in amalgam is transported via wastewater to the sewage sludge at water treatment plants and bodies of water. Mercury from dental amalgam is also released into the environment from the smoke gases of crematories.

The toxic impacts of dental amalgam have been studied quite extensively, but no scientific evidence of its health risks have been observed in the population in general. For this reason, conservation of the environment has been given as the primary reason for ending the use of amalgam. In Finland, the use of amalgam has decreased each year, and its use is now very limited. Even so, the use of amalgam has some indications, where it is considered more durable and affordable than other filling materials, and it still has a user group. However, Norway's experiences concerning a full ban on the use of amalgam have demonstrated that an alternative material can always be found to replace amalgam in all situations and, ultimately, terminating its use was not considered problematic in Norway.

The EU Mercury Regulation requires that no later than on 1 July 2019 each of its Member States presents a national list of measures it intends to implement to phase-out the use of amalgam preferably completely by 2030. Ending the use of amalgam in Finland is possible, but it will require multisector cooperation for example in the areas of materials development, communication and training. This document presents Finland's national plan with measures that will be necessary for phasing-out the use of amalgam by 2030.

#### 2 EU mercury legislation

#### 2.1 Minamata Convention

The Minamata Convention on Mercury is a global treaty to protect human health and the environment from the adverse effects of mercury agreed on by the UN in 2013. By mid-December 2018, 1010 countries including all EU Member States has ratified the Convention. All EU Member States have committed to integrating the Convention in their own legislation and implementing the Convention. The primary objective of the Convention is to protect the population's health and the environment from the hazardous impacts of mercury by minimising mercury sources caused by humans. The coordinated implementation of the Convention is expected to result in a reduction in the environment's mercury levels over time. In addition to cutting down on the use other sources of mercury, the Convention obligates signatory countries to reduce the use of dental amalgam or preferably to end its use completely by 2030.

# 2.2 Regulation of the European Parliament and of the Council (EU) 2017/852, Article 10

In May 2017, the EU Member States adopted the Mercury Regulation (Regulation of the European Parliament and of the Council (EU) 2017/852), which is based on the objectives of the Minamata Convention. The Regulation is applied as is as legislation. However, the Member States have been provided certain obligations concerning the implementation of the Regulation. Article 10 or the Regulation provides the following in the use of dental amalgam

- 1. From 1 January 2019, dental amalgam shall only be used in pre-dosed encapsulated form.
- From 1 July 2018, dental amalgam shall not be used for dental treatment of deciduous teeth, of children under 15 years and of pregnant or breastfeeding women, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient.
- 3. By 1 July 2019, each Member State shall set out a national plan concerning the measures it intends to implement to phase down the use of dental amalgam. Member States shall make their national plans publicly available on the internet and shall transmit them to the Commission within one month of their adoption.

- 4. From 1 January 2019, operators of dental facilities in which dental amalgam is used or dental amalgam fillings or teeth containing such fillings are removed, shall ensure that their facilities are equipped with amalgam separators for the retention and collection of amalgam particles, including those contained in used water.
  - Such operators shall ensure that amalgam separators put into service from 1 January 2018 provide a retention level of at least 95 % of amalgam particles. From 1 January 2021, all amalgam separators in use provide a retention level of 95%. Amalgam separators shall be maintained in accordance with the manufacturer's instructions to ensure the highest practicable level of retention.
- 5. Dental practitioners shall ensure that their amalgam waste, including amalgam residues, particles and fillings, and teeth, or parts thereof, contaminated by dental amalgam, is handled and collected by an authorised waste management establishment or undertaking. Dental practitioners shall not release directly or indirectly such amalgam waste into the environment under any circumstances.

# 2.3 Decision by the Parliament on amendments to Acts related to the implementation of the Regulation of the European Parliament and of the Council (HE 78/2018 vp, EV 59/2018 vp)

On 26 June 2018, Finland's Parliament approved the Government's proposal for amendments to the Chemicals Act, the Waste Act, the Environmental Protection Act, the Health Care Professionals Act, and the Criminal Code of Finland so that they include provisions on the measures required for the implementation of the Regulation of the European Parliament and of the Council on Mercury, such as provisions on a supervisory authority, a competent authority and the sanctions resulting from violating the obligations laid down in the Regulation. Technical adjustments were also made to the Chemicals Act and the Waste Act. The Acts entered into force on 1 September 2018.

# 3 Amalgam and its potential impacts on health

Amalgam is a general term used of all alloys, which include mercury. Mercury appears in three forms, metallic mercury, inorganic mercury compounds and organic mercury compounds. In room temperature metallic mercury is liquid, shiny and silver white. Liquid mercury is highly likely to turn into toxic, odourless mercury vapour. Vapour is absorbed quickly via the respiratory system and spreads throughout the body via the circulatory system (Spencer 2000, Park & Zheng 2012). Acute and chronic exposure to mercury can cause many health impacts, such as gingivitis, a cough, a fever, shaking, hallucinations, insomnia, neurocognitive impairments and changes in personality (Counter & Buchanan 2004, Park & Zheng 2012).

Metallic mercury is retained, in particular, in the liver, kidneys and central nervous system, and it can penetrate both the blood–brain barrier and the placenta (Park & Zheng 2012, Bridges & Zalups 2017). In spite of mercury levels generally being low in hair, blood and urine, they can be high in the kidneys and the brain (Danscher et al. 1990). The estimated half-life of mercury in the human brain is approximately 20 years (Park & Zheng 2012).

Dental amalgam was developed in France in the 1830s and it has been used in filling of cavities for nearly 200 years. Dental amalgam contains silver, tin, copper, zinc and metallic mercury (SCENIHR, 2008). Even though the mercury contained in dental amalgam is in a very stable form, it is still the human body's most significant source of mercury (Bjorkman et al. 2007, Fisher 2003). Amalgam fillings release mercury as vapour mostly when applied or removed, but small amounts are also released as inorganic ions due to wear caused by biting and due to corrosion. Mercury vapour can be absorbed to the body via the respiratory system and inorganic ions via the digestive system. After it has been absorbed, mercury spreads to various organs via the circulatory system. (Park & Zheng 2012)

The amount of mercury released from dental fillings depends on the size of the filling, the surface of the tooth on which the filling is located, the quality of the amalgam, the age of the filling and the structure and temperature of the food that is consumed (Bates 2006, Skare & Engqvist 1994). The mercury content of brains of deceased persons has been found to correlate with the number of tooth surfaces on which they have amalgam fillings (Mutter 2011, Bjorkman et al. 2007). The toxic impacts of amalgam have been studied quite extensively, but no scientific evidence of chronic mercury poisoning or other health risks have been observed in the population in general. However, it has been considered that mercury may be associated with higher

risk of, for example, kidney diseases (Mortada et al. 2002), as well as neurological diseases such as Parkinson's and Alzheimer's disease (Hsu et al. 2016, Sun et al. 2015). Children and pregnant women are particularly susceptible to the harmful impacts of mercury (Bjornberg et al. 2005).

The benefits of amalgam are its durability and affordability. Amalgam withstands biting forces and the filling's seam tightness improves over time, for which reason, the replacement of amalgam fillings is not recommended. What is more, removal of a filling causes greater mercury exposure than leaving the filling in. A small portion of the population present a mercury allergy with reactions on oral mucosa, which is a valid reason for replacing amalgam fillings. Careless handling of amalgam can also in the long term lead to occupational health risks. (BIO Intelligence Service 2012)

# 4 Environmental burden caused by dental amalgam

The use of dental amalgam accounts for 24 per cent of all mercury use in the EU and it is a significant source of released mercury (Mudgal et al. 2012). The mercury contained in amalgam is transported via wastewater to the sewage sludge at water treatment plants and bodies of water, where it accumulates in fish and other aquatic organisms. Mercury from dental amalgam is also released into the environment from the smoke gases of crematories. When released in the environment, mercury can turn into methylmercury, which is one of mercury's most toxic forms. Methylmercury is enriched in the food chain and causes the greatest damage to predators and humans, who are at the top of the food chain. The conservation of the environment has been given as the primary reason for the need to completely ban the use of amalgam.

A reduction on the use of amalgam and the careful treatment of waste amalgam have notably reduced the environment's mercury load in recent years. In 2011, 0.5 mg/kg of mercury was measured in the sewage sludge at Viikinmäki and Suomenoja wastewater treatment plants in Helsinki, which is below the target value of 1.0 mg/kg. (HSY, 2012) Amalgam fillings can last for decades, which means that the removal of old fillings will cause a mercury burden to the environment for a long time to come.

#### 5 Use of dental amalgam in Finland

Dental amalgam was used in Finland as a primary dental restorative material until the end of the 1980s, when the use of composite resins exceeded that of amalgam. A recommendation drawn up by the National Research and Development Centre for Welfare and Health's (STAKES) expert group published in 1993, stated that the use of amalgam should be reduced for environmental reasons and that amalgam should only be used when other restorative materials were not indicated. In 2005, the European Commission published the EU Mercury Strategy, which included a proposal for reducing or completely banning the use of dental amalgam due to its environmental impacts. According to the EU Regulation that entered into force in May 2017, as of 1 July 2018 the use of amalgam for the dental treatment of deciduous teeth, of children under 15 years and of pregnant or breastfeeding women. The exception to this is when a dental practitioner deems it strictly necessary based on the specific medical needs of the patient. The use of amalgam in bulk form was prohibited on 1 January 2019, and it can only be used in pre-dosed, encapsulated form. Amalgam still has a small loyal group of users in Finland.

### 5.1 Current Care Guidelines on dental restoration

The Current Care Guidelines on dental restoration (28 May 2018) states the following:

When a tooth is being prepared for a filling, the extent of the damage should be the primary criteria for determining the need for preparation. The most suitable restorative and filling method should be selected on the basis of the extent and location of the damage, in mutual understanding with the patient. The most common restorative is composite resin. Other restoratives include glass ionomer cement, amalgam, ceramic materials and gold. The production of new amalgam fillings is not recommended, because an effort is being made to end the use of amalgam in accordance with international agreements. The replacement of old fully functional amalgam fillings is also not recommended especially for patients in high caries risk. The use of amalgam fillings can be considered in limited indications for the restoration of molars that are subject to occlusion stress in adult patients with a high risk of caries. Fillings produced outside the mouth (indirect restoration) are a sustainable alternative in cases of extensive damage especially in the molar area.

A study of Finland's patient records in health centres has provided information on the durability of fillings in practice. No differences were observed in the lifetimes of

composite fillings and amalgam fillings (Palotie *et al.* 2017). The composite filling produced with the correct indications and meticulous technique has been found to be durable (Heintze & Rousson 2012).

# 5.2 Study by the Ministry of Social Affairs and Health and the Ministry of the Environment 2012

According to a study (Sandström, 2012) drafted together by the Ministry of Social Affairs and Health and the Ministry of the Environment in 2012, the sale of amalgam has declined during the 2000s, and its use in Finland is limited. More than half (57%) of dentists who responded to the survey said that they used some amalgam. On average, amalgam fillings accounted for only 2.6% of all prepared fillings.

The majority of dentists felt that amalgam could be replaced with other filling materials, but 43% said that amalgam could not be replaced in certain situations. Respondents said that they used amalgam due to its ability to withstand moisture, its durability and its price, and primarily to repair difficult cavities in molars and cavities that reached deep into the gum line. Other reasons listed for its use included occlusion-related reasons, a request by the patient, the repair of old amalgam fillings, resin allergy, retrograde fillings, poor oral hygiene, high caries risk and in cases where the restoration area is particularly difficult to keep dry. Dentists also stated that the price of fillings produced with indirect restoration (ceramic, gold) was notably higher for patients and that Finnish social insurance institution (Kela) does not subsidise the use of these materials or dental laboratory costs even though they would often be much more durable.

There were no significant differences between responses from health centres and private surgeries concerning the use of amalgam. On the basis of the study, it was determined that amalgam can be replaced with alternative restoratives, if the possible rise in treatment costs is taken into consideration.

#### 5.3 Current state

In May 2019, in order to determine current use of dental amalgam, an email survey was sent out to a sample of chief dentists of Finland's cities and joint municipal authorities, private service providers, materials suppliers and materials researchers as well as all universities that provide basic studies in dentistry. Responses were provided by seven cities or joint municipal authorities (Helsinki, Kuopio, Kuusamo, Oulu, Joint Municipal Authority for North Karelia Social and Health Services (Siun Sote), Tampere, Turku, Vaasa), the Finnish Student Health Service (FSHS), one private service provider chain, four materials researchers and three universities.

#### 5.3.1 Public service providers

On the basis of responses provided by public service provider, the share of amalgam used in all fillings in 2018 was marginal, less than a per mille. The use of amalgam has been discontinued completely in Oulu, Turku and Kuopio and very nearly discontinued in Vaasa and Tampere. The share of amalgam fillings produced by the city of Kuusamo and the Siun Sote area accounted for a per mille of all fillings produced. Use by the City of Helsinki has decreased every year for the past five years and, in 2018, the city only ordered two packages (Table 1). In 2018, only 36 cavities were repaired with amalgam fillings in Helsinki's health centres, which was 0.27% of all fillings. The FSHS used amalgam in a few fillings in 2018, but ordered no new amalgam that year.

Year	Number ordered (packages)
2018	2
2017	2
2016	22
2015	33
2014	37

Table 1. Number of amalgam packages ordered by the City of Helsinki in 2014–2018. One package contains 50 amalgam capsules. There are three capsule sizes, which contain 0.4g, 0.6g and 0.8g of amalgam.

Public service providers stated that the primary indication for the use of amalgam fillings was the repair of old amalgam fillings and support teeth for prostheses when it is not possible to produce more durable laboratory-made crowns. All the respondents felt that it was possible to completely end the use of amalgam by 2030. However, respondents expressed concern due to the rise in costs caused by replacing materials, the potential environmental impacts of composite resins, the increased need to replace fillings and the more time-consuming production of them.

#### 5.3.2 Private service providers

Of private service providers, one service provider chain and a dental practice located in a sheltered housing unit for mentally disabled persons provided responses to the survey.

The use of amalgam in the service provider chain had declined each year and had been mostly marginal in 2018. The dental practice located in sheltered housing for the mentally disabled had not used dental amalgam at all for several years. The most commonly used restorative by the sheltered housing unit was glass ionomer. The responses in question viewed a complete end to the use of amalgam as completely possible.

#### 5.3.3 Restorative suppliers

On large supplier provided information on sale of restoratives. According to acquired information, the share of restorative sales that amalgam has accounted for over the past two years has been negligible, approximately 0.001 %. Thus, ending the sale of amalgam will not have any significant impact on restorative sales.

#### 5.3.4 Teaching at universities

Three universities that provide dentistry studies responded to the survey. All those universities still teach the preparation of amalgam fillings during a course on restorative caries treatment, but with limited indications. According to the instructions, an amalgam filling can be considered if the filling will be subjected to hard occlusal pressure, the edge of the filling will be located under the gum and there are difficulties in keeping the treatment area dry, or if the patient has a high risk of secondary caries (e.g. a patient with hyposalivation). However, amalgam fillings are mostly produced for a dental model in the exercise and not for a patient. The purpose of teaching amalgam filling preparation is primarily to introduce students to amalgam as a material. This is considered necessary because there are still many amalgam fillings in patients' mouths that have to be repaired or removed. Removal of an amalgam filling is considered appropriate when repairing the old filling is not possible. All universities also teach the correct handling and recycling of amalgam waste.

All the responding universities stated that it would be possible to completely end the use of amalgam by 2030. Reasoning for this included that composite-based restoratives and bonding products have developed considerably over the decades and that meticulous work and correct use will ensure that composite fillings are durable. In certain indications, glass ionomer was also considered a good alternative

restorative for amalgam. Ceramic fillings produced outside the mouth were considered very good alternatives for amalgam in extensive molar fillings. The computer-assisted production of ceramic fillings at dentists' practices is growing in number, and they are often more affordable than traditional laboratory produced restoratives. One response stated that digital production and 3D printing are modern day solutions and by 2030 there may be more new innovations in use.

#### 5.3.5 Restoratives research

Finnish researchers carry out internationally recognised research that aims to develop the long-term durability of restorative materials and bonding products that will replace amalgam. Material development aims mostly to improve resistance to breakage, to development of antimicrobial characteristics, self-cleaning surfaces, more durable bonding and bio-adhesives. Also, under development are 3D printing technology and artificial intelligence-steered robotics for the production of fillings.

The development of composite resins, new restorative options and filling methods were considered very important before the use of amalgam could be completely terminated. In addition to their multiple benefits, composite resins also have some shortcomings, such as their subpar durability compared to amalgam in occlusion, the faster wear of the filling compared to tooth enamel, leaks at seams caused by shrinking during light-curing as well as their moisture sensitivity and the related technical challenges during the procedure. Ceramic or gold fillings produced outside the mouth were considered the only really good alternative for amalgam in more extensive fillings in the molar area. However, these are currently considerably more expensive than fillings made from direct technique restoratives.

The key challenge for ending the use of amalgam was believed to be the costs of fillings produced outside the mouth as well as the lack of appropriate equipment and expertise in the health care sector. The best option to replace amalgam was considered to be the development of direct restorative materials that has similar longevity and dental tissue protecting qualities than fillings made outside of the mouth. The environmental impacts of restoratives use and production were also considered important.

#### 5.4 Treatment of amalgam waste

Amalgam waste is classified as hazardous waste that can cause danger or harm to the environment or human health even in low concentrations due to their chemical or other characteristics. Pursuant to the Waste Act, the party that produces hazardous waste must see to its collection and transport to a location authorised to treat hazardous waste according to the guidelines given by waste management supervisory authority.

A Government resolution in 1997 contains provisions on the handling and treatment of wastewater from dentists' surgeries and waste that contain amalgam (112/1997). After this, dental care units have only been permitted to pour wastewater in sewers through an amalgam separator, the separation capacity of which is at least 95%. Separators must be emptied at least once a year. According to a study carried out in 2012, an estimated 1,060g of amalgam accumulated in separators at each treatment unit each year. According to information acquired from a company that collects amalgam waste, a total of around 400 kg of waste accumulates in all of Finland's separators each year. The amount of waste has remained consistent in recent years, but each year a larger share of waste has consisted of materials other than amalgam. An example of such waste is the sand in soda blowers, which can fill the separator very quickly.

Ninety-nine percent of the service providers who responded to the survey in 2012, and all of the service providers who responded in 2019, reported that they had statutory amalgam separators and that waste from these separators was placed appropriately in hazardous waste collection. When new treatment units are gradually acquired, separators with 95% separation capacity will be replaced with separators with a capacity of 98%.

However, more attention should be given than at present to the handling of removed teeth that have amalgam fillings and other secondary amalgam waste (e.g. amalgam capsules and contaminated cotton swabs). In the Ministry of the Environment study in 2012 only 62% of dentists reported that they put their secondary waste into hazardous waste collection or gave it to the maintenance company at the time their separator was exchanged. Accordingly, some health centres stated in 2019 that they still threw away secondary waste with their mixed waste.

# 6 International perspectives and experiences on ending the use of amalgam

Dental amalgam is still used extensively in many EU Member States, and it is a significant source of environmental mercury emissions in the EU area. Amalgam is used predominantly due to its lower costs, durability and reasons related to the education and expertise of dentists and the equipment at their practices. Also the fact that scientists have not been able to find conclusive evidence on amalgam's adverse effects on human health has made dentists' unwilling to terminate the use of amalgam. (SCENIR 2008) Of the EU Member States Sweden and Denmark and of non-EU members at least Japan, Norway, Switzerland, Australia and Canada have set limitation on or completely prohibited the use of amalgam (Mudgal et al. 2012).

#### 6.1 Norway's example

In 2003, guidelines entered into force in Norway that prohibited the use of amalgam as a primary restorative option in any fillings. In 2008, a full ban on the use of products that contained mercury, including dental amalgam, entered into force. However, during the transition period until 2011, amalgam could be used in fillings prepared during general anaesthesia or for patients who were allergic to other restorative materials. Amalgam can still be used for individual patients when absolutely necessary, but this requires authorisation from the Norwegian Climate and Pollution agency Klif. However, only a very small number of permissions have been applied.

The use of amalgam was limited in Norway even before the ban. The 840kg used in 1995 had decreased by 95% 5o 43 kg in 2007. A study carried out before the ban found that many Norwegian dentists used amalgam as their primary option in large molar fillings. Dentists had a more positive attitude on the use of amalgam than the population in general, and plans to implement a complete ban encountered resistance at first. However, views of the ban became more positive over time.

A follow-up study published in 2012 found that dentists had replaced amalgam predominantly with composite resins as was expected. It was believed that the production of composite restoratives took 15–45 minutes longer than the production of amalgam restoratives. The control of moisture when preparing a filling was

considered challenging occasionally. After the full amalgam ban entered into force, the number of reports on the adverse health impacts of composite restoratives increased somewhat, but not in the same relation as the use of composite fillings increased.

The use of composite resins instead of amalgam was estimated to have increased overall prices on average by 51 euros per filling. Costs included the higher price of the restorative (6.50 euros), longer dentist visits (43 euros), investments in new instruments (0.30 euros) and training costs (1.50 euros). The increased worktime spent on production of fillings, which was tied to the size of the filling, had a significant impact on costs. It was also found that if the lifetime of composite fillings is shorter than that of amalgam fillings, this "extra" renewal of a filling will add 103 euros to the overall costs. If, instead, ceramic or gold were chosen as a restorative material, the costs would naturally be much higher. Effectively, all dentists had used also other than amalgam filling material previously regularly, thus they did not need to invest in new instruments or training due to the complete ban.

Generally speaking, dentists and patients were satisfied with the use of alternative restoratives and did not feel that the full ban on the use of amalgam was a negative thing. Some of the considered benefits of the use of composite fillings were the reduced need to remove healthy dental tissue, as well as the client's satisfaction with the used restorative. Also, the reduced exposure to mercury in the workplace was considered a positive point. The shorter lifetime of the direct restoration materials used as alternatives for amalgam, as well as the challenges related to their use in some indications were considered as negative points. At the end of the report, it was stated that the purpose for ending the use of amalgam was predominantly to reduce the environment's exposure to mercury, and a ban should be seen from a more extensive perspective than as just a decision between a dentist and their patient. At that time, it was estimated that there was still around 10,000 kg of amalgam in the teeth of Norwegians.

The paragraph's text is based on a report commissioned by the Norwegian Climate and Pollution Agency (Klif) " Skjelvik J., Review of Norwegian experiences with the phase-out of dental amalgam", which was published in May 2012.

# 7 Aspects that must be taken into account in Finland when drawing up the national plan

The Council of European Dentists (CED) has proposed that the following points be taken into account when drawing up the national plan for phasing out the use of amalgam.

#### 7.1 Need for investments

In Finland, there will be a need for investments in the following areas:

- The need for recycling of waste resulting from removal of old fillings will
  continue for decades. Investments in recycling (emptying of separators, service
  and upgrades as well as the recycling of secondary waste) will be needed for a
  long time to come even if the production of new fillings were terminated now.
- 2. The cost of fillings may rise somewhat, if the durability of new alternative restoratives produced with direct procedures prove to be subpar compared to amalgam in challenging indications, and fillings need to be renewed more often.
- 3. A larger volume of indirect restorations (restoratives produced outside the mouth, e.g. ceramic) should be produced in health centres, and the subsidising of prices must be considered for private service provider charges. The increasing production of indirect restorations may also increase the need for new equipment procurements and training.
- 4. Investments must be made in the development of new durable restoratives and bonding procedures.
- Communication on the environmental impacts and other negative impacts of amalgam and on the schedule for phasing out the use of amalgam will require some resources.

#### 7.2 Current use of amalgam

Based on the survey conducted in 2019, the estimated share of amalgam out of all restorative materials used in Finland is considerably less than 1%, perhaps even tenths of a percentage. Dentists who use amalgam, generally use it only for indications where the use of alternative restoratives is more difficult. Amalgam is used

due to its cheaper costs, mostly for fillings along the gum line and in the posterior part of the mouth. Amalgam is not used for children, young people under 15 years of age and, as a rule, not in cases of new dental caries cavities. All suction systems have ready-installed amalgam separators with a separation capacity of at least 95%. The Regional State Administrative Agency supervises the use of separators.

In the future, the use of amalgam should be monitored with similar surveys approximately every three years.

### 7.3 Prevention of caries and provision of information

One method for reducing the use of amalgam is setting national objectives for caries prevention, and health promotion that aims to reduce cavities and concomitantly the need for restorative treatment.

The Current Care Guidelines on the prevention of caries published on 22 September 2014, which all dentists must comply with. According to the guideline, caries can be controlled primarily with a healthy lifestyle, which includes brushing one's teeth with fluoride toothpaste twice a day, maintaining a regular meal rhythm and avoiding snacking between meals, drinking water when thirsty and protecting small children from contracting Streptococcus mutans bacteria at an early age. The habits and lifestyle that promote the control of caries should be taught to children at a young age when they are easiest to adopt. People of all ages must also be given the opportunity to live in an environment that is safe for their oral health, to make healthy decisions and to learn positive models for healthy behaviours from their community. The risk of cavities can be greater for those with diseases or medications that reduce salivation. This will require most effective preventive measures. An effort is made first and foremost to stop the spread of any caries damage that has appeared. If stopping the damage from spreading is unsuccessful, only then will the damage be repaired with a filling.

Preventive measures generally reduce the need for fillings and are, for this reason beneficial and necessary. Measures to prevent caries should specifically be focused on people in lower socioeconomic classes and with multiple diseases, as the prevalence of caries is greater in these groups. Preventive measures will have little impact on amalgam use as such, as even its current use is scarce.

#### 7.4 Funding

The public financing model will, to some extent, affect the use of amalgam and the model should be reviewed and reformed over coming years keeping this in mind.

- 1. Amalgam is a more affordable for service providers than other restorative materials and takes a shorter amount of time to prepare. However, pursuant to the Decree on Client Fees the charge for treatment in a health centre is the same no matter what material is used. The same applies to the sum of compensation paid by the social insurance institution of Finland that subsidises private service costs. The procedure compensation that dentists in the public sector receive for one filling is also the same regardless of what direct procedure restorative they use. For this reason, the current situation encourages both health centre and private practice dentists to use amalgam, because an amalgam filling, which is faster to produce and of which material costs are lower, brings in the same amount of income as a composite filling. Pricing in the private sector is not regulated, and the client's co-payment varies according to the price. However, the common practice of the private sector is to set the same price for amalgam fillings as for e.g. composite fillings. In conclusion, the financing model does not favour ending the use of amalgam, nor encourage patients to choose an amalgam filling since the price is the same for all direct restoratives.
- 2. The most durable options for large posterior cavities are fillings produced outside the mouth with an indirect procedure, such as ceramic and gold fillings. Their production by public service providers is still quite limited, and their costs are not subsidised at the moment by health insurance compensation when accessing services from private service providers. Extending health insurance compensations to fillings produced outside the mouth should be considered and their production should be increased in the public sector. This will require not only monetary investments, but also investments in further training and the equipment and materials required for their production.
- The Health Care Act does not specify that preventive dental care is free of charge in all instances, although preventive health care is otherwise free of charge. This must be amended so that the need for dental restoration will decline in general.
- Research that aims at the development of more sustainable restoratives and bonding products that are alternatives for amalgam must be encouraged and supported.
- Ending the use of amalgam will gradually reduce costs related to handling and recycling of waste, but this will possibly take decades. It will also reduce the occupational health risks related to the use of amalgam.

## 7.5 Education of dentistry students and continuous training of professionals

The Minamata Convention proposes that trade unions and parties that provide teaching of dentistry ensure that dentists are able to use restoratives other than amalgam fillings and promote their use. In Finland, this is included in the basic education and continuous training of dentists. The dentistry units at universities primarily teach the preparation of restoratives other than amalgam. However, all teaching units do teach both the preparation and removal of amalgam fillings at least once.

For example, Dutch, Swedish and Norwegian universities no longer teach their students to make amalgam fillings, and the universities actively collaborate in work to end the use of amalgam. National cooperation with universities in promoting the phasing out of amalgam use should be increased in Finland as well, and universities should plan to phase out the teaching of preparation of new amalgam fillings..

Dentists already in the labour force must be provided training to improve their awareness of the harmful impacts of amalgam use, the correct treatment of amalgam waste (in particular secondary waste) and the national effort to end the use of amalgam.

## 7.6 Research and development of alternative filling materials use

The promotion of restoratives research and development is one method for reducing the use of amalgam. Composite fillings still require significant improvements such as better endurance in occlusion, better resistance to wear, prevention of seam leakage, reduced moisture sensitivity and the simplification of other treatment techniques. The current restoratives for direct procedures should be developed so that their characteristics can compete with those produced indirectly. Additionally, new material options and restorative treatment procedures must be developed.

Finnish researchers are working on long-term restorative development focusing specifically on the durability and enhanced bonding of restoratives alternatives to amalgam, as well as on new production techniques. Material research should be supported increasingly, as it not only endorse efforts to end the use of amalgam, but it is also of great importance to the population's health.

#### 7.7 Treatment of amalgam waste

In Finland, the preparation of new amalgam fillings is very limited. Waste that contains mercury is predominantly produced when amalgam fillings and teeth with the fillings are removed. The use of amalgam separators is compulsory, and their use is supervised by the Regional State Administrative Agency. The amalgam waste collected from separators and the majority of secondary waste are transported to hazardous waste treatment facilities.

However, there is still room for improvement in the handling and recycling of secondary amalgam waste, as some waste containing amalgam still ends up in mixed waste. The burden resulting from amalgam waste can be eliminated with communication and education.

#### 7.8 Supervision

A new subsection (4) has been added to section 24 of the Health Care Professionals Act pursuant to which the National Supervisory Authority for Welfare and Health (Valvira) and the Regional State Administrative Agency will supervise compliance with the prohibitions and restrictions on the use of dental amalgam laid down in the Mercury Regulation. The amendment entered into force on 1 September 2018. The supervision of dental amalgam use is a new task for Valvira and the Regional State Administrative Agency.

Valvira also sees to the national steering and supervision of health care professionals. The Regional State Administrative Agency is responsible for the steering and supervision of health care professionals in their areas of jurisdiction. Valvira coordinates the activities of the Regional State Administrative Agencies with the aim of harmonising their operating principles, approaches and practical solutions. Valvira handles matters related to the steering and supervision of health care professionals especially in instances where the matter has extensive impacts or when there is a suspicion of a medical error. If a dentist neglects their obligation laid down in the same Act to perform tasks for which their education or skills can be considered inadequate or acts erroneously or reprehensibly in some other manner, Valvira can impose sanctions of varying severity. These can include the issuing of specific regulations and instructions for professional activity, imposing restrictions on the right to practise professional activity, and the withdrawal of the right to practise the profession of a licensed professional. In less serious cases, Valvira and the Regional State Administrative Agency can give the health care professional an admonition or

draw his or her attention to appropriate professional practice. According to section 33 of the Act, Valvira can issue a written warning.

The Health Care Professionals Act contains provisions on obligations related to professional ethics and on acting contrary to these. According to section 15 of the Act, in their professional activities, health care professionals must apply generally accepted and ethically justified methods. If a dentist violates Article 10, sections 1 and 2 of the Mercury Regulation, it would, as a rule, be a violation of section 15 of the Health Care Professionals Act. In this case, the National Supervisory Authority for Welfare and Health (Valvira) and the Regional State Administrative Agency may issue sanctions pursuant to section 26 of the Health Care Professionals Act.

Article 10, section 4 of the Mercury Regulation includes provisions on the requirements for amalgam separators and section 6 on arranging the handling and collection of amalgam waste. In this regard, compliance with provisions is supervised by the Centres for Economic Development, Transport and the Environment (ELY Centres) and the municipalities' environmental protection authorities. Non-compliance with the Waste Act is a fineable offence.

The Ministry of Social Affairs and Health is the authority that will draw up the plan of measures for the phasing out of the use of dental amalgam. The ministry is tasked with its sector's general planning, steering and supervision pursuant to laws such as the Primary Health Care Act (66/1972), the Act on Specialised Medical Care (1062/1989) and the Health Protection Act (763/1994).

# 7.9 Consent of patients and entering this into patient records

The reasoning for the selection of restorative materials and a note that the selection was made in mutual understanding with the patient should be marked down in records on the patient visit. In Finland, amalgam is primarily used in exceptional situations. All the respondents to the 2019 survey said that if the decision is made to use amalgam when selecting the restorative material, they will always discuss the reasons with the patient or the patient's guardian, and the information will be marked down in patient records.

It is likely that some patients will misunderstand the environmental reasons behind the phasing out of amalgam use and will request that their sound amalgam fillings should be removed. As a rule, this treatment is unnecessary and contrary to the patient's

interests. The National Current Care Guidelines for dental restorative treatment (published 28<sup>th</sup> of May 2018) no longer recommends the use of amalgam. The Current Care Guidelines and the Avoid Wisely Guidelines state the following on the replacement of amalgam fillings: "the replacement of fully functional amalgam fillings is not recommended because they are considered safe with regard to the patient's general health, and because the seams of composite fillings on permanent bicuspids and molars are more likely to crack than amalgam fillings".

#### 7.10 Communication

The correct way of providing information to the population will likely support the phasing out of amalgam use. It may also be that dentists are not entirely aware of the hazardous environmental impacts of amalgam, which means that communication is vital. However, it is important that communication related to ending the use of amalgam also highlights that this is due to environmental factors and that there is no proof of any health risks related to amalgam. The entire population needs to be informed extensively on the reasons for ending the use of amalgam and that it is unnecessary to get existing fillings replaced.

To ensure proper information distribution, a national communication plan must be drafted. Communication channels may include press releases, news in professional publications, training events for professionals, television, radio, public websites and social media.

#### 8 National action plan

The national long-term objective is to terminate the use of amalgam in Finland by 2030. The short-term objective is to reduce use of amalgam nationally at least 25% from the 2019 level by 2022, 50% by 2025 and 75% by 2028. Ending the use of amalgam by 2030 will require a coordinated and comprehensive multisectoral approach.

The following measures will be implemented with the aim of attaining set objectives:

- A working group will be appointed at the beginning of 2020 to coordinate
  measures for phasing out the use of amalgam and to monitor the attainment of
  the objectives. Dentists who carry out clinical work, university representatives,
  as well as representatives from trade unions, environmental organisation and
  communications professionals will be invited to take part in planning.
- A preliminary communications plan will be drafted by the end of 2019.
   Communication to the public and professionals will begin at the beginning of 2020.
- 3. Dialogue will be held with universities that provide dentistry studies to end teaching of production of amalgam fillings.
- 4. Training will be arranged for oral health care professionals on the environmental impacts of amalgam and matters related to phasing out its use.
- 5. Steps will be taken to prevent oral diseases.
- 6. The research on development of restorative and bonding materials will be supported.
- 7. A set of instructions will be drafted that dentists must follow when removing amalgam fillings (e.g. the use of dental dams and protective goggles, cutting the filling into pieces that are as large as possible, effective ventilation, protection of the dentist's and the oral hygienist's skin).
- 8. Assessment and follow-up: Plans will be put in place for effective monitoring and follow-up processes. Indicators will be designed for follow-up and the necessary data will be collected and analysed to see if the objectives are being met. Survey on the use of amalgam and the treatment of waste will be carried out every three years.

#### 9 Conclusions

Although no scientific evidence is found on health hazards related to dental amalgam, it is known that amalgam is an important source of mercury both for the human body and the environment, and that mercury is a dangerous environmental toxin. Even if the use of amalgam in new fillings ended today, the environment's mercury-exposure would continue for at least 30 years due to existing amalgam fillings.

The use of dental amalgam in Finland has decreased each year and today it is used in less than a per mille of all fillings. The majority of dentists do not make amalgam fillings at all, and those who do only do so when they feel there is no other option. Norway's example proves that, ultimately, phasing out the use of amalgam has not been seen as a problem, but rather that alternatives for amalgam have been found in all indications.

Ceasing the use of dental amalgam in Finland would be possible even at a faster phase than what is required by the Minamata Convention, due to its limited use and the other material options available. However, this will require multisectoral cooperation, training and communication as well as investments in the introduction of sustainable materials that can replace amalgam. Additionally, investments must be made in health promotion and preventive care, that can as such reduce the need for restorative treatment.

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