

DENTAL **AMALGAM** **IN THE EU**

HEADING TOWARDS
A PHASE OUT?

Mercury regulation: EU's response to the Minamata convention

On 17th May 2017, the EU institutions formally adopted the new regulation on mercury that was published on 24th May 2017 in the Official Journal as Regulation (EU) 2017/852. It will apply as of 1st January 2018.¹

The EU Mercury Regulation seeks to align EU law with the provisions of the International Convention on Mercury (Minamata Convention), which was initiated by The United Nations Environment Programme in 2009 and signed in 2013.² The Minamata Convention covers all aspects of the mercury life cycle, from primary mining to waste disposal, including trade provisions and rules for artisanal and small-scale gold mining (ASGM), products containing mercury, and mercury emissions into the air.

The EU Mercury Regulation focuses on filling gaps in EU legislation so that it becomes compliant with the Minamata Convention; this includes:

- The import of mercury
- The export of certain mercury-added products
- The use of mercury in certain manufacturing processes
- New mercury uses in products and manufacturing processes
- Mercury use in artisanal and small-scale gold mining (ASGM)
- **Mercury use in dental amalgam (fillings)**

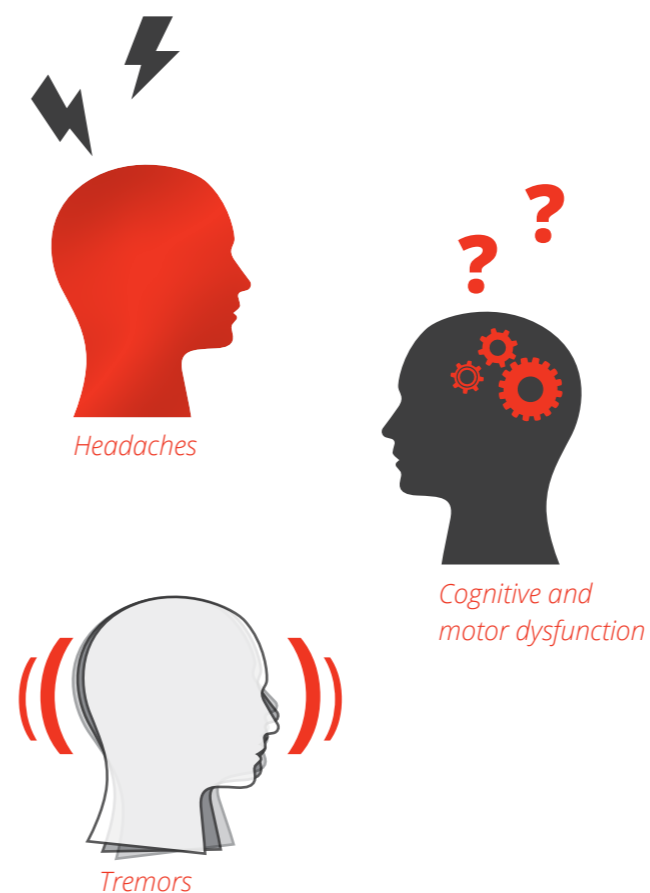
How does mercury affect us?

The World Health Organisation (WHO) itemises the following key properties and characteristics about mercury in its Factsheet:³

- Mercury is a naturally occurring element that is found in air, water, and soil
- Exposure to mercury – even small amounts – may cause serious health problems, and is a threat to the development of the child in utero and early in life
- Mercury may have toxic effects on the nervous, digestive, and immune systems, and on lungs, kidneys, skin, and eyes
- Mercury is considered by WHO as one of the top ten chemicals or groups of chemicals of major public health concern
- People are mainly exposed to methylmercury, an organic compound, when they eat fish and shellfish that contain the compound

In that same Factsheet, WHO details the effects of mercury exposure as follows: “Elemental and methylmercury are toxic to the central and peripheral nervous systems. The inhalation of mercury vapour can produce harmful effects on the nervous, digestive and immune systems, lungs and kidneys, and may be fatal. The inorganic salts of mercury are corrosive to the skin, eyes and gastrointestinal tract, and may induce kidney toxicity if ingested”.³

Typical symptoms following the inhalation, ingestion, or when mercury comes in contact with the skin includes tremors, insomnia, memory loss, headaches, and cognitive and motor dysfunction.³



Dental amalgam: The largest source of mercury in the EU

Dental amalgam used in fillings is a combination of 50% elemental mercury, 35% silver, and trace amounts of tin, copper, and other metals. The concern with dental amalgam is that it does not degrade, therefore contributing to the accumulation of mercury in the environment globally, and two thirds of mercury used in dental amalgam is re-released into the environment (SWD, page 10).⁴

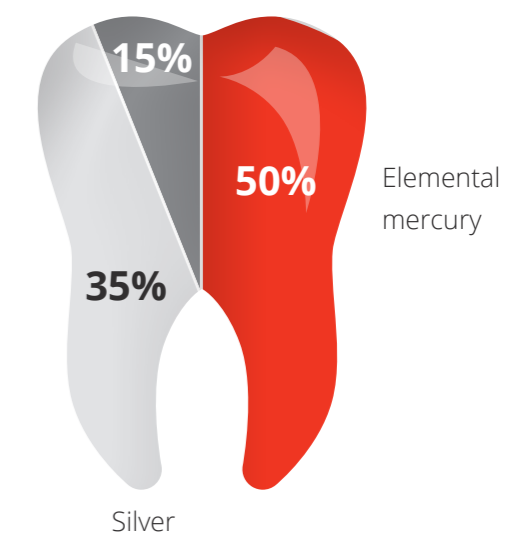
As mercury is phased out in the EU chlor-alkali industry in principle (officially by the end of 2017), dental amalgam has now become the largest source of mercury in the EU, with current usage estimated at 75t/y (SWD, page 143).⁴

For the majority of the population, dental amalgam fillings are the largest source of exposure to mercury; according to the European Commission, previous studies report that there is over 1,000 tonnes of mercury in people's mouths in the EU (SWD, page 157).⁴

Despite the large amounts of mercury used in dentistry in the EU, and the threats posed to the environment and human health by mercury, the Commission estimates that only 69% of waste produced from dental amalgam is managed as hazardous waste (SWD, page 163).⁴

Dental amalgam filling composition

Other (tin, copper, other metals)



Understanding the achievements in the EU

The mercury regulation: A partial phase out of Dental amalgam

Article 10 of the Mercury Regulation addresses the issue of dental amalgam, its key provisions are:

JAN 2018

- **1st January 2018:** Dental practitioners will have to ensure that their amalgam waste (amalgam residues, particles, fillings, teeth, or parts contaminated by dental amalgam) is handled and collected by an authorised waste management establishment. Releasing amalgam waste into the environment will be prohibited under any circumstances.
- **1st July 2018:** A phase out - Dental amalgam will not be used to treat milk teeth and will be prohibited for the treatment of children younger than 15 years, as well as for pregnant or breastfeeding women. There is only one exception - if the use of dental amalgam is deemed strictly necessary by the dental practitioner - this professional discretion must be based on the specific needs of the patient.

- **1st January 2019:** Dental amalgam will only be used in pre-dosed encapsulated form, mercury in bulk form will no longer be an option for dental practitioners.*

**Historically, dentists mixed amalgam on-site using bulk liquid mercury and metal powders, but today dental amalgam is increasingly purchased in pre-dosed amalgam capsules in different sizes; the mercury content of which can vary from 100mg - 1,000mg.*

A recent survey by the Council of European Dentists (CED) suggested that: "in terms of use, 17 European countries reported 100% use of pre-dosed capsules [...] another four reported very high percentages (65-95%), while another four provided no estimates" (SWD, page 36).⁴

Table 1: The use of dental amalgam in the EU

	Share of dental amalgam in 2010 (in % restorations)	Expected share of dental amalgam in 2025 (in % restorations)	Dental mercury use in 2010 (t)	Projected dental mercury use in 2025 (t)
Denmark, Estonia, Finland Italy, and Sweden	0-5%	0%	0.3-0.4	0
Bulgaria, Belgium, Cyprus, Germany, Hungary, Ireland, Latvia, Luxembourg, The Netherlands, Portugal, and Spain	6-35%	5-15%	9-12	3-8
Austria, Czech Republic, France, Greece, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia, and the UK	>35%	20-30%	46-78	23-35

Source: SWD/2016/017 final - 2016/023 (COD) Commission Staff Working Document Ratification and Implementation by the EU of the Minamata Convention, page 35.⁴

- **1st January 2019:** Dental facilities using dental amalgam or removing dental amalgam from fillings/teeth will have to ensure that they are equipped with amalgam separators for the retention and collection of amalgam residues, including those contained in used water. (See Table 2)

JAN 2019

- **1st July 2019:** Each Member State will have to set out a national plan with measures on how it intends to implement a phase down of dental amalgam. Member States will have to digitally upload their national plans and transmit them to the European Commission within one month of their adoption.

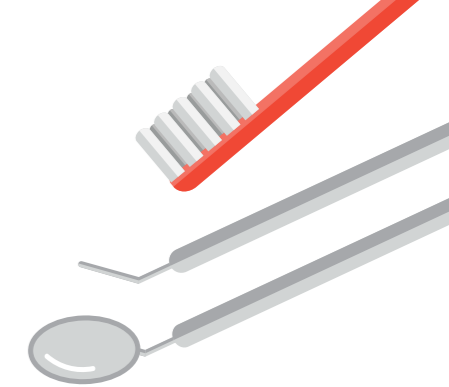


Table 2: Existing dental amalgam legislation in EU Member States

According to the EU Manual of Dental Practice (2015), published by the Council of European Dentists, 22 out of the 28 EU Member States already have binding legislation requiring the use of amalgam separators.⁵

Country	Legal Requirement?	Comment	Since
AUSTRIA	Yes	Actively enforced.	1995
BELGIUM	Yes		2002
BULGARIA	No	Amalgam separators are only advised, not mandatory.	
CROATIA	Yes	The EU Hazardous Waste Directive is incorporated into law and actively enforced. Amalgam separators are legally required.	
CYPRUS	Yes	Cyprus adopted the European legislation on waste disposal in 2005. The disposal of clinical and hazardous waste is collected and managed by a licensed company. The public dental service and all private practices have a contract with a private company for the safe disposal of clinical and hazardous waste.	2005
CZECH REPUBLIC	Yes	The dental office must have the contract with an accredited company for the disposal of amalgam and exchange of the separators. The disposal of clinical hazardous waste must be ensured by an accredited company. Amalgam separators have been obligatory since 2004, as part of a dental unit.	2004
DENMARK	Yes	The Hazardous Materials Act is very strict – and covers the use/disposal of amalgam. Only approved companies or individuals are allowed to collect amalgam. The dentist must have written documentation for their disposal and to whom. The municipality (kommune) provides guidance. Amalgam separators are generally mandatory.	
ESTONIA	No	Amalgam separators are not required by law, although they are advised.	
FINLAND	Yes	The EU Hazardous Waste Directive was incorporated into Finnish law in 1993. Amalgam separators have been legally required since 1997.	1993
FRANCE	Yes	The EU Hazardous Waste Directive has been incorporated into French law and amalgam separators have been legally required since 1998 in all units, requiring the collection of 95% of the weight of the amalgam in waste water. There are regulations restricting who collects the waste to registered or licensed carriers.	1998
GERMANY	Yes	There are regulations to cover the disposal of clinical waste as well as a special Directive concerning amalgam separators and permission to load used water into public systems. Amalgam separators have been obligatory since 1990.	1990
GREECE	Yes	Amalgam separators are required by a Common Ministerial Decision in 2003 - "Handling and Management of Hazardous Waste Materials Regulations" - covers the disposal of clinical waste.	2003

HUNGARY**	Yes	The EU Hazardous Waste Directive has been fully transposed into national law, therefore requiring amalgam waste to be collected as a hazardous waste. The law is actively enforced in practice. Governmental guidance on environmental management states waste amalgam should be stored and carried as bio-hazardous. Dental amalgam is collected by registered and licensed carriers; it is separated from other hazardous dental waste. Dentists (or the owners of the practice) are liable for the procedure. Collected amalgam waste is recycled, whilst amalgam scrap (mixed amalgam not used for the filling) is also collected but carried as bio-hazardous waste separately – it is also recycled. Amalgam separators are not required by law for existing units, but are where new units are equipped. Separators are recommended or advised by environmental management policies for all units. By 2013, approximately 70% of practices were equipped with centrifugal or tank-type separators.	
IRELAND	No	Clinical waste is stored for a month at the practice and given to a sanitary waste company at the end of every month. X-Ray liquids and amalgam are normally disposed of once a year. There is a specific document in which these operations should always be logged and described, and records kept about stored quantities. Amalgam separators are not compulsory by law.	
ITALY	No	Clinical waste is stored at the practice and given to a sanitary waste company at the end of every month. X-Ray liquids and amalgam are normally disposed of once a year. There is a specific document in which these operations should always be logged and described, and records kept about stored quantities. Amalgam separators are not compulsory by law.	
LATVIA	Yes	Operations with hazardous waste are determined by the Hazardous Waste Law. The necessity and installation of the amalgam separator are determined by the Regulations issued by the Cabinet regarding the adequacy of medical institutions. Dental practices must have an agreement with companies stating that they are authorized to collect these wastes.	
LITHUANIA	No	The EU Hazardous Waste Directive has been incorporated into law and actively enforced. Amalgam separators are not mandatory and amalgam is not popular with patients or dentists.	
LUXEMBOURG	Yes	The EU Hazardous Waste Directive is incorporated into law and is actively enforced. Amalgam separators are legally required.	
MALTA	Yes	The EU Hazardous Waste Directive is incorporated into law and actively enforced. Amalgam separators are legally required.	
NETHERLANDS	Yes	Disposal of clinical waste may only be carried out by certified companies. Regulations for Health and Safety based on Guidelines for Infection Control inoculation against Hepatitis B are mandatory for dental workers. Amalgam separators have been required in practices by law since 1997.	1997
POLAND	Yes	The EU Hazardous Waste Directive has been transposed into Polish law, regulations restrict the collection of waste dental amalgam to registered carriers. Amalgam separators are not compulsory by law.	
PORTUGAL	No	At a national level, there is some regulation that recommends the use of the amalgam separators. But this is not legally mandatory. The spirit of the law points out the importance of its use, in order to improve the achievement of complete equipment by the dental professionals.	
ROMANIA	No	There are special orders of the Ministry of Health relating to the disposal of clinical waste. There is compulsory verifiable collection and incineration of biohazard-contaminated medical and dental waste. Amalgam separators are not required by law.	
SLOVAKIA	Yes	The EU Hazardous Waste Directive is incorporated into law and actively enforced. Amalgam separators are legally required.	
SLOVENIA	Yes	The EU Hazardous Waste Directive is incorporated into law and actively enforced. There is compulsory contracting with special companies who transport and dispose of waste. Amalgam separators are legally required.	
SPAIN**		Since 1986 it has been mandatory to fit amalgam separators to all newly equipped premises or newly installed units. This requirement extends to putting in older units in new premises. However, there may be differences in the autonomous regions towards compliance.	1986

SWEDEN	Yes	If waste is not disposed of according to national regulations, the dentist is liable. Amalgam separators have been required by a national law, since January 1999. The requirement applies to all units or premises.	1999
UNITED KINGDOM	Yes	Clinical waste is considered “hazardous” under the Hazardous Waste (England and Wales) Regulations 2005. Similar regulations cover Scotland and Northern Ireland. Clinical waste has to be collected by a licensed company along with appropriate documentation, including waste descriptions and the relevant waste codes. Clinical waste will either be incinerated or rendered safe before final disposal. The regulations also mean that all dental amalgam waste is classified as hazardous waste and, as such, discharge to sewer is not allowed. To comply with the regulations, dental practices (both existing and new) require amalgam separation units to be installed and ensure the amalgam collected is disposed of in accordance with the regulations.	
Current legal requirements for amalgam separators in the EU Member States, and Norway, Iceland, and Switzerland			
ICELAND	Yes	The EU law on the disposal of clinical waste is enforced. Since 2000, amalgam separators have been mandatory and there are regulations for the safe disposal of clinical waste.	2000
NORWAY	Yes	Waste amalgam must be collected by a registered carrier. Amalgam separators have been required by law since 1996.	1996
SWITZERLAND	Yes	Whilst the Swiss are not enacting the EU Directive, there are regulations to cover the disposal of clinical waste, including the installation of amalgam separators. Amalgam separators have been required by law for many years.	

(**New units only)

Source: EU Manual of Dental Practice (2015), Council of European Dentists

Key recommendations

- **National action plans mandated by the Mercury Regulation (to be completed by July 2019) will be vital:** Setting national objectives for minimising dental amalgam use is an important first step.
- **Awareness must be raised amongst practitioners:** i.e. dentists and in particular, their dental associations. This will be crucial in ensuring real progress is made. When planning their amalgam phase down, Nordic countries experienced some initial resistance from the dental industry and this largely because they were:
 - Unaware of the environmental impacts of mercury from amalgam, and the social benefits of reducing mercury emissions
 - Initially reluctant to invest in new equipment required to reduce mercury pollution or to support mercury-free fillings
 - Initially unconvinced of the durability of alternative filling materials
 - Inconsistent with their skills and knowledge in applying mercury-free techniques
- **Education will play an important role:** Dental school curricula should be updated to promote mercury-free dentistry.
- **The insurance market will need to adapt:** Public and private insurance systems in the EU should be adapted to help favour mercury-free dental fillings. For example, Sweden withdrew financial support for mercury amalgam fillings from the national dental insurance service. The cost to the patient was subsequently equal to if not higher than a composite restoration, resulting in a near full phase-out of the use of dental amalgam.
- **A gradual approach is needed:** EU Member States should see the phase-out of dental amalgam for vulnerable groups (coming into effect in July 2018), as a first step towards a full phase-out.

References

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