REPORT ON LAWS AND RECOMMENDATIONS ON DENTAL MERCURY MANAGEMENT IN THE EU

31/01/2018

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Contents

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1. Introduction

This report is comparing the Regulation (EU) 2017/852 of the European Parliament and of the Council of the 17 May 2017 with the current situation of handling dental amalgam in the EU countries according to "Study on the potential for reducing mercury pollution from dental amalgam and batteries", BIO Intelligence Service, European Commission, 2012.
The EU has decided on a new regulation concerning mercury which entered into force 1 January 2018 (REGULATION (EU) 2017/852 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/20089.

The Commission should assess and report on the feasibility of a phase out of the use of dental amalgam in the long term, and preferably by 2030, taking into account the national plans required by this Regulation and whilst fully respecting Member States' competence for the organisation and delivery of health services and medical care.

This means, inter alia, that:

- ✓ amalgam may only be used in pre-dosed, encapsulated form from 1 January 2019 children under the age of 15 and pregnant or breastfeeding women may not be treated with amalgam unless it is considered absolutely necessary for medical purposes, from 1 July 2018

- ✓ amalgam separators with a specific efficacy must be fitted at dental establishments where amalgam is used or amalgam fillings are removed, from 1 January 2019

- ✓ 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.

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2. Phasing out the use of dental amalgam

Regulation (EU) 2017/852 of the European Parliament and of the Council of the 17 May 2017:
The use of mercury in dental amalgam is the largest use of mercury in the Union and a significant source of pollution. The use of dental amalgam should therefore be phased down in accordance with the Convention and with national plans based, in particular, upon the measures listed in Part II of Annex A to the Convention. The Commission should assess and report on the feasibility of a phase out of the use of dental amalgam in the long term, and preferably by 2030, taking into account the national plans required by this Regulation and whilst fully respecting Member States' competence for the organisation and delivery of health services and medical care. Furthermore, particular preventive health protection measures should be taken for vulnerable members of the population, such as children and pregnant or breastfeeding women.
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.

Current situation in dental clinics within the Member States ("Study on the potential for reducing mercury pollution from dental amalgam and batteries", BIO Intelligence Service, European Commission, 2012):

Hg-free alternatives to dental amalgam can be used in most medical conditions, but are still not widely used in a number of Member States. The main reasons are as follows:

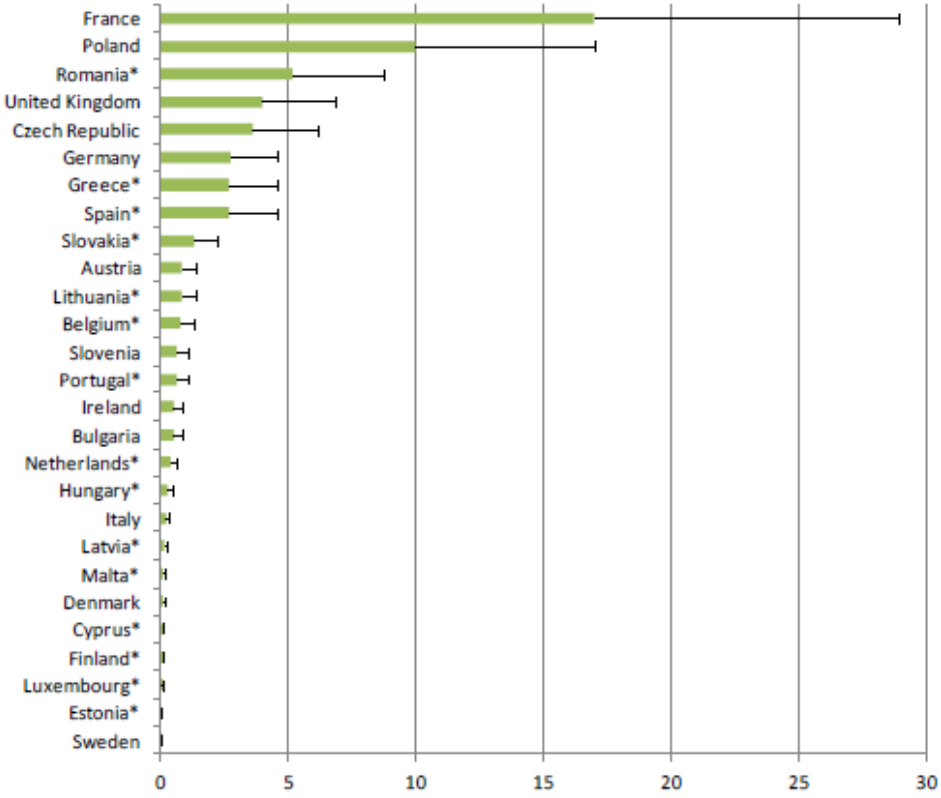
- ✓ Hg-free alternatives are more expensive for patients
- ✓ Dentists are not properly trained conducting Hg-free alternatives
- ✓ Dentists are not aware of the benefits of Hg-free materials
- ✓ Dentists consider that hg-free fillings have a lower durability
- ✓ Dentists are not reluctant to change their current practice to invest in new equipment required to handle Hg-free fillings
  (p 12)

Hg-free materials are estimated to be used in 66% of restorations in the EU countries (p 54).

The quantity of mercury contained in people´s mouths in the EU Member States has been estimated to over 1 000 tonnes (p 155).
The technical development of dental equipment with high-speed drills replacing more slowly rotating drills in technically advanced nations has increased mercury emitted to air or released to water when removing or replacing amalgam fillings. This is caused by smaller particles created by the high-speed drills. In addition, the higher speed drills results in higher temperatures, increasing the emission rate. The temperature may to some extent be controlled by cooling with e.g water. However, this results in larger amounts of mercury in water leaving the clinic (p 156).

France appears to have the highest consumption of dental amalgam, at some 30% of the total EU demand. Together with Poland these two countries seem to account for almost 50% of dental amalgam in the EU (statistics from 2003 and 2006, so the figures may have changed) (p 51).

Figure 4: Demand for dental mercury in EU Member States (t Hg/year)



Source: Data provided by national dental associations and/or health authorities via the study questionnaire, taken from previous studies or estimated by BIO using available data.
*Estimated by BIO

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3. Use of encapsulated dental amalgam

Regulation (EU) 2017/852 of the European Parliament and of the Council of the 17 May 2017:

Only pre-dosed encapsulated dental amalgam should be allowed for use, and the use of amalgam separators in dental facilities in which dental amalgam is used or dental amalgam fillings or teeth containing such fillings are removed should be made mandatory, in order to protect dental practitioners and patients from mercury exposure and to ensure that the resulting waste is collected and disposed of in accordance with sound waste management and under no circumstances released into the environment. In this respect, the use of mercury in bulk form by dental practitioners should be prohibited. Amalgam capsules such as those described in European standards EN ISO 13897:2004 and EN ISO 24234:2015 are considered to be suitable for use by dental practitioners.

From 1 January 2019, dental amalgam shall only be used in pre-dosed encapsulated form. The use of mercury in bulk form by dental practitioners shall be prohibited.

Current situation in dental clinics within the Member States ("Study on the potential for reducing mercury pollution from dental amalgam and batteries", BIO Intelligence Service, European Commission, 2012):
There are two main ways to prepare dental amalgam: by using pre-dosed capsules or by mixing dental alloy and mercury purchased as separate products. The reason why some dentist is still using the system with dental alloy in powder is that buying this is cheaper than easy-to-use capsules (p 156).
Surplus amalgam from the preparation phase, which is directly discarded as waste is estimated above at approximately 11 t/year by dental practices (p 160). 70% is assumed managed as hazardous waste, 30% as non-hazardous waste (p 163)
According to a survey by the CED (Council of European Dentists) in 2010 the use of encapsulated dental amalgam was required in 12 of 23 EU-countries (p 51).

4. Use of amalgam separators

Regulation (EU) 2017/852 of the European Parliament and of the Council of the 17 May 2017:

Furthermore, a minimum level of retention efficiency for amalgam separators should be set. Compliance of amalgam separators should be based on relevant standards, such as European standard EN ISO 11143:2008. Given the size of economic operators in the dentistry sector affected by the introduction of those requirements, it is appropriate to provide sufficient time to adapt to the new requirements.

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:
(a) amalgam separators put into service from 1 January 2018 provide a retention level of at least 95 % of amalgam particles;
(b) from 1 January 2021, all amalgam separators in use provide the retention level specified in point (a).

Amalgam separators shall be maintained in accordance with the manufacturer's instructions to ensure the highest practicable level of retention.

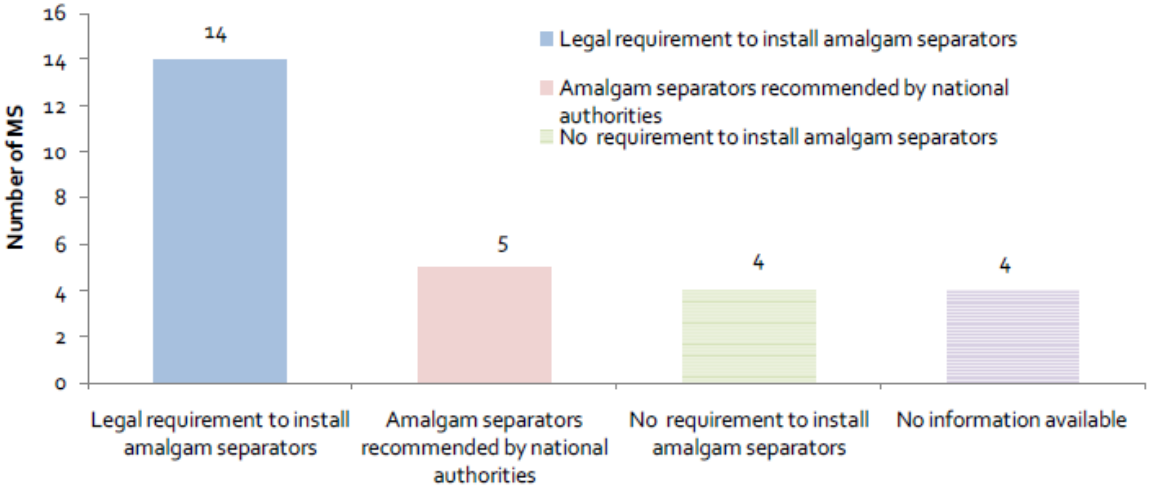
Current situation in dental clinics within the Member States ("Study on the potential for reducing mercury pollution from dental amalgam and batteries", BIO Intelligence Service, European Commission, 2012):

Information is still missing for Member States with large population (e.g Poland, Spain). It is assumed that 75% of dental facilities are equipped with amalgam separators (p 160).
Most dental practices are equipped with chairside traps and vacuum filters (p 157). 95% of the mercury discharges to the vaccum pump system goes to the chairside filters and vacuum pump filters, while 5% goes directly to the sewer. Chairside filters and vacuum pump filters together have an average mercury removal efficiency of 45% (p 160)
There are legal requirements to install amalgam separators in the following countries: Austria, Belgium, Czech Republic, Germany, France, Finland, Italy, Latvia, Malta, Netherlands, Portugal, Sweden, Slovenia and United Kingdom. This requirement applies to both new and existing practices and a 95% minimum efficiency is required. (p 39, 158)
In some Member States amalgam separators are installed voluntarily under guidance provided by the national authorities (Denmark, Ireland) (p 158).

In ten Member States 100% of dental facilities are equipped with amalgam separators: Austria, Czech Republic, Denmark, Germany, Finland, Latvia, Malta, Portugal, Sweden and United Kingdom

It is estimated that approximately 34 200 additional dental clinics will have to install a separator, assuming an average number of 2.1 dentists per clinic (p 88).
Standard efficiency of amalgam separators is 95%, but actual efficiency is assumed to be lower due to a lack of proper maintainance observed in many cases (p 160). It is roughly estimated that the average efficiency is 70% (p 42). It is estimated that approximately 53 000 dental clinics will need to significantely improve the maintainance of their equipment (p 89).

Figure 13: Requirements concerning installation of amalgam separators



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5. Training

Regulation (EU) 2017/852 of the European Parliament and of the Council of the 17 May 2017:
The training of dentistry students and dental practitioners on the use of mercury-free alternatives, in particular for vulnerable members of the population such as children and pregnant or breastfeeding women, as well as the carrying out of oral health research and innovation in order to improve knowledge of existing materials and restoration techniques, and to develop new materials, can help in reducing the use of mercury.

Current situation in dental clinics within the Member States ("Study on the potential for reducing mercury pollution from dental amalgam and batteries", BIO Intelligence Service, European Commission, 2012):

Some of the key obstacles identified are the unequal levels of dentist´s environmental awareness concerning the mercury issue and the unequal skills of dentists in Hg-free techniques. Some Member States would benefit from the experience gained in Nordic Member States where Hg-free fillings have been used for a longer period of time (p 48).

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6. Restrictions vulnerable patients

Regulation (EU) 2017/852 of the European Parliament and of the Council of the 17 May 2017:
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.

Current situation in dental clinics within the Member States ("Study on the potential for reducing mercury pollution from dental amalgam and batteries", BIO Intelligence Service, European Commission, 2012):

- ✓ Sweden: general ban on dental amalgam since 2009.
- ✓ Denmark: Ban on the use of dental amalgam for children´s milk teeth and all front teeth.
- ✓ Germany: It is recommended not to use dental amalgam on children, pregnant and nursing women.
- ✓ France: Recommendation to avoid dental amalgam use in pregnant and breastfeeding women.
- ✓ Italy: Limits of using amalgam in children under the age of 6, in pregnant and feeding women.
- ✓ Catalonia, Spain: Recommendation not to use dental amalgam in pregnant women and children under 14 years old.
  (p 147)

7. Waste management

Regulation (EU) 2017/852 of the European Parliament and of the Council of the 17 May 2017:
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.

Current situation in dental clinics within the Member States ("Study on the potential for reducing mercury pollution from dental amalgam and batteries", BIO Intelligence Service, European Commission, 2012):
Mercury in dental waste represents about 50 t/year. It is estimated that 45 t/year from dental practices and up in chairside effluents, with only a part of which being captured and treated as hazardous waste in compliance with EU legislation. (p 41). The removal of old amalgam fillings is the main source of dental amalgam released to wastewater. During the placement of new amalgam fillings, there is also some surplus of amalgam that is discharged to wastewater (p 156).
Out of the 52 t Hg/year of waste produced it can be estimated that around 36 t/year (69%) are managed as hazardous waste, 3 t/year (7%) as biomedical waste and 13 t/year (24%) as non-hazardous waste (p 163).
It can be estimated that current and historical use of dental amalgam leads to:

- ✓ 16-23 t Hg/year emitted to the air
- ✓ 2-4 t Hg/year emitted to surface water
- ✓ 16-24 t Hg/year emitted to the soil and groundwater
- ✓ 31-46 t Hg/year sequestered for long-term or recycled (p 175)

15 t Hg/year are captured by the sewage sludge and 1 t Hg/year is found in the WWTP effluent discharged to surface water (p 165).
Surveys have shown that dental waste is sometimes treated as municipal waste and/or medical waste, even though mercury-containing waste and sludge from dental clinics should be considered as hazardous waste according to EU waste legislation (EU waste code 18 01 10, "dental amalgam waste"). This may cause significant mercury emissions to air, water and soil/groundwater (p 162)
The past accumulation of mercury in piping system of dental clinics over many years may constitute another source of continuous releases to wastewater (p 157)

8. Summary requirements vs current situation amalgam separators and hg-fillings

	Legal requirements separators	**Separators recommended by authorities**	**100% equipped with separators**	**90-100% equipped with separators**	**Unknown equipped with separators**	**Hg-free alternatives not widely used**	**Restriction from authorities not to use hg in vulnerable patients or a total ban**	**Share of dental amalgam 2010 more than 35% of restorations**
Austria	X		X					X
Belgium	X			X				
Bulgaria					X			
Croatia								
Cyprus				X				
Czech Republic	X		X			X		X
Denmark		X	X				X	
Estonia					X			
Finland	X		X					
France	X			X		X	X	X
Germany	X		X				X	
Greece					X	X		X

Hungary					X			
Ireland		X			X			
Italy	X			X			X	
Latvia	X		X					
Lithuania					X			X
Luxembourg					X			
Malta	X		X					X
Netherlands	X			X				
Poland					X	X		X
Portugal	X		X					
Romania					X	X		X
Slovakia					X			X
Slovenia	X			X				X
Spain					X	X	X	
Sweden	X		X				X	