

# The Minamata Convention on Mercury, the EU Regulation and dental amalgam and you!

The Minamata Convention on Mercury is a global treaty whose aim is to minimise, and where possible eliminate, the adverse effects of man-made emissions and releases of mercury and mercury compounds into the environment.

The European Union approved the Convention in adopting Regulation (EU) 2107/852 of the European Parliament and of the Council on 17th May 2017. An EU Regulation is immediately enforceable as law in all EU States simultaneously and is binding in its entirety and, as such, the Regulation entered into Irish law on 1st January 2018.

The Department of Communications, Climate Action and Environment is the lead Department for this new Regulation as it is the aim of the European Commission, by means of this Regulation, to minimise and, where feasible, ultimately eliminate global anthropogenic mercury releases to air, water and land (Recital 4). Article 10 of the Regulation stipulates the law in relation to dental amalgam and the timelines for the changes laid out in Recitals 21-23 of the Regulation.

## From 1st January 2018:

- Amalgam separators put into service from that date shall provide a retention level of at least 95 % of amalgam particles (Article 10, 4 (a)). Compliance of amalgam separators should be based on relevant standards, such as European standard EN ISO 11143:2008 (Recital 22).
- 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 (Article 10, 6).

## From 1st 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 (Article 10, 2).

## From 1st 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 (Article 10, 1). 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 (Recital 22).

- 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 (Article 10, 4).

## From 1st 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 (Article 10, 3).

## From 1st January 2021:

- all amalgam separators in use shall provide a retention level of at least 95 % of amalgam particles (Article 10, 4 (b)).

## Summary: Regulation (EU) 2107/852

DATE	ACTION
1st January 2018	<ul style="list-style-type: none"> <li>All amalgam separators installed from now must have at least a 95% amalgam particle retention level</li> <li>Waste management shall ensure that dentists do not release waste amalgam into the environment under any circumstance</li> </ul>
1st July 2018	Very restricted use of dental amalgam in deciduous teeth, those under 15 and pregnant and breastfeeding women
1st January 2019	<ul style="list-style-type: none"> <li>Dental amalgam shall only be used in encapsulated form</li> <li>All dental facilities working with dental amalgam must have an amalgam separator</li> </ul>
1st July 2019	National Plan for the phase down of dental amalgam
1st January 2021	All amalgam separators in use shall have a retention level of at least 95%

### Guidance on continued use of amalgam in dental practice

Dental amalgam is a significant contributor to overall EU environmental emissions of mercury from human activities. The decision to restrict the use of dental amalgam in the chosen groups is the start of the phase down and ultimately, the phase out of dental amalgam by 2030 for environmental reasons. There is no evidence base to restrict its use on health grounds.

The restriction on the use of dental amalgam for pregnant or breastfeeding dental patients, in deciduous teeth and those patients under 15 may present challenges to dentists, who are obliged to work in their patients' best interest. A range of alternative approaches is available and these should be discussed with the patient (or parent/guardian). Treatment options you may discuss will include:

- Available restorative materials, such as glass ionomers and composite resins, for the management of caries in deciduous and permanent teeth
- Alternative restorative options, such as selective caries removal, minimum intervention dentistry or preformed metal crowns (including the Hall technique for deciduous teeth)

- Alternatives to restoration, such as sealants or caries arresting measures (such as silver diamine fluoride in deciduous teeth)
- Postponing or delaying treatment. Minimising dental treatment remains the standard for pregnant women where this is appropriate to the health of the mother and foetus.
- Extraction

You may consider that the use of amalgam is 'deemed strictly necessary ... based on the specific medical needs of the patient'. Such a need may be founded on:

- Medical history, including allergy to non-amalgam restorative materials
- Patient management that may only allow amalgam placement
- Dental treatment under general anaesthetic
- High caries rate or risk that contraindicates other approaches
- Size, number or morphology of the restoration that precludes other approaches
- Inability to achieve moisture control for alternative measures

### A number of outcomes may arise in this situation:

- you may decide that dental amalgam is the best material and the patient and/or their parent/guardian gives consent for you to proceed on an agreed basis. Ideally, this will be done before treatment commences but occasionally, may be necessary to have this discussion in the course of treatment.
- Alternatively, you may not be able to justify the use of a mercury-free material in a particular situation or may believe that it is not within your competence to place the material requested by your patient satisfactorily. You should advise the patient and/or their parent/guardian of your decision and offer them a referral to another dentist who may be able to complete the treatment satisfactorily using an alternative restorative material, technique or treatment outcome
- Or, your patient and/or their parent/guardian may request a second opinion.



It is essential that you record your conversation, decision and its justification in your patient's clinical record. You should also record a valid consent from the patient (or guardian). Your records should include details on your conversation around the status of dental amalgam in relation to the EU Regulation and the reasons for suggesting the use of dental amalgam as opposed to alternative materials or treatments, the comparative costs and prognosis.

### **Guidance on replacement and disposal of amalgam in dental practice**

The Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), independent scientific committees managed by the Directorate-General for Health and Consumer Protection of the European Union, accept that dental amalgam is an effective, safe dental restorative material and that there is not enough evidence to support its immediate replacement by mercury-free restorative materials.

The use of amalgam separators and the management of all hazardous waste are already enshrined in Irish law (S.I. 126 of 2011, European Communities (Waste Directive) Regulations 2011). In addition, the management of amalgam waste is described in the Dental Council's Code of Practice relating to: Infection Prevention and Control (2015), 4.2 Amalgam.

While amalgam separators are now ubiquitous in Irish dental practices, this may not be the case where mobile or surgical suction systems are used, for example, where treatment takes place under sedation or general anaesthesia. In these settings, it is likely that amalgam is released while sectioning or removing teeth containing amalgam restorations. The regulations do not provide for any exception to the use of amalgam separators so dentists should ensure that clinical waste that may contain amalgam is appropriately treated.

Extracted teeth with amalgam fillings must be treated as mercury-containing waste and be disposed of accordingly (Dental Council's Code of Practice relating to: Infection Prevention and Control (2015) 4.2.6). All dental healthcare professionals must be familiar with the appropriate methods for the handling of and the safe disposal of dental amalgam in order to safeguard the environment.

### **Guidance on the EU Regulation and patient health**

As a mercury-added product dental amalgam is an environmental threat. However, EU Regulation 2107/852 raises a number of potential questions around health for the public.

Some patients will be concerned that because certain groups have been selected already in the phase out of dental amalgam it must mean that all dental amalgam fillings are a health hazard. The Scientific Committee on Emerging and Newly Identified Health Risks

(SCENIHR) stated that "there is no justification for removing clinically satisfactory amalgam restorations as a precaution, except in those patients diagnosed as having allergic reactions to amalgam constituents".

All medical and dental treatment for pregnant women should only be carried where necessary; this is international standard practice.

Infant exposure to mercury in the placenta is higher than in breast milk. The FDA concluded that infants are not at risk from breast milk of women exposed to mercury vapour on the placement or removal of dental amalgam.

Dental amalgam is being phased down and phased out for environmental reasons. There is scientific and clinical concern that the present mercury-free materials require continuing development and investigation.

The implementation of preventive regimes to minimise the risk of caries and the need for restorations is universally accepted to be the best oral health care approach. It falls to every dental professional to guide and encourage their patients in caries prevention.

### **IDA Statement**

The IDA, in common with the World Dental Federation (FDI) and the Council of European Dentists (CED), supports the phasing-down of dental amalgam as outlined in the Minamata Convention. The IDA calls on the Government and the dental community to:

- Champion disease prevention and health promotion, thereby reducing the need for dental restorations;
- Encourage dental education in the best, evidence-based management of dental caries and restoration of teeth once damaged by dental caries;
- Ensure that third party schemes permit clinical autonomy in the choice of dental restorative materials by means of contractual and financial structure, allowing dentists to continue to act in the best interests of their patients;
- Support ongoing research into restorative dental materials in the search for cost-effective, durable and safe alternatives to dental amalgam;
- Acknowledge the need for on-going research on the health and environmental impact of alternative dental restorative materials;
- Insist on the full declaration of the chemical composition of alternative dental restorative materials by manufacturers.