

## **EU submission to the Minamata Secretariat on dental amalgam pursuant to paragraph 4 of COP-3 Decision MC-3/2 (Dental Amalgam)**

The measures taken at EU level to implement a phase-down of dental amalgam are set out in Regulation (EU) 2017/852 on mercury, as follows:

### **1. Article 10(1): Mercury in pre-dosed, encapsulated form**

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

### **2. Article 10(2): Vulnerable population**

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. Article 10(3): Member State phase-down plans**

Each Member State was required to set out by 1 July 2019 a national plan concerning the measures it intends to implement the phase-down the use of dental amalgam. Member States were required to make their national plans publically available on the internet and transmit them to the Commission within one month of their adoption.

Regulation (EU) 2017/852 on mercury does not provide a format for national phase-down plans.

To date, 23 Member States have set up their national plans for the phase-down of the use of dental amalgam. These have been made publically available and can be found on CIRCBC.

### **4. Article 10(4): Dental amalgam separators**

From 1 January 2019, operators of dental facilities in which dental amalgam is used for 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)

## **5. Article 19(b): Review of the feasibility of a phase-out of dental amalgam**

The Commission reported in August 2020 to the European Parliament and to the Council on the outcome of its assessment regarding the feasibility of a phase-out of the use of dental amalgam in the long term, and preferably by 2030 (see [Commission Report COM\(2020\)378](#)).

This report concludes that:

- The phase-out of the largest remaining use of mercury in the EU - dental amalgam - is technically and economically feasible, before 2030. Progressive substitution of dental amalgam with mercury-free materials is occurring without policy intervention as patients, in general, and increasingly dentists, prefer mercury-free fillings. Nevertheless, without legislative action, significant amounts of dental amalgam are still expected to be used in the coming years. This would prolong the associated environmental and health issues associated with the current use of dental amalgam, including significant emissions of mercury to air.
- Both phase-down and phase-out of dental amalgam require addressing a number of issues, including improving the understanding of specific medical conditions where dental amalgam should continue to be allowed, increasing the information on available mercury-free materials and gathering further data on emissions of mercury, associated to the use of dental amalgam.
- Therefore, the Commission will present to the European Parliament and the Council in 2022 a legislative proposal to phase-out the use of dental amalgam. The preparatory work will include the assessment of the need for accompanying measures, such as reducing emissions of mercury associated to the use of dental amalgam and enhancing the availability of information on mercury-free dental fillings.