

World Alliance for Mercury-Free Dentistry Всемирный альянс за стоматологию без ртути Alliance Mondiale pour une Dentisterie sans Mercure Alianza Mundial por una Odontología Sin Mercurio التحالف العامي لطب أستان غل من الزنيق 世界无汞牙科联盟





# Developing National Plans to Phase Down Dental Amalgam Use in the EU Member States

Per the requirements of the EU Mercury Regulation 2017/852 of 17 May 2017, Article 10.3, dental amalgam:

"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."



4 April 2019

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### **1** Introduction

The largest consumer use of mercury in the European Union is dental amalgam, which is also a significant source of pollution. Since mercury does not degrade, dental amalgam further contributes to the accumulation of mercury in the global environment, with negative impacts on humans, fish and wildlife.

Now that most other major uses and releases of mercury have either been eliminated or significantly curtailed, the EU Mercury Regulation 2017/852 requires EU Member States to phase down the use of dental amalgam. Beyond banning its use for children under the age of 15, pregnant women, and breastfeeding mothers, the Regulation further requires that by July 2019 Member States "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."<sup>1</sup>

Meanwhile the European Commission has taken the next obvious step and is anticipating the complete phase-out of dental amalgam by launching a study on the "Assessment of the feasibility of phasing out dental amalgam". The conclusions of this study will form the basis for a report which will be presented by 30 June 2020 to the European Parliament and the Council of the EU.

Because mercury-free dental filling materials are already available, effective and affordable, the main question now is simply "how long before a complete phase-out of dental amalgam?". Therefore, Member States' national plans are a prime opportunity not only to lay out near-term measures for phasing down dental amalgam use, as required by the Mercury Regulation, but also to prepare for the inevitable phase-out of dental amalgam in the European Union.

This guide presents concrete and cost-effective measures to assist Member States in developing the required national plans to phase down dental amalgam use. But it also takes the next obvious step and explains why a complete phase-out of dental amalgam use – strongly supported by the European public – can and should be an integral part of each national plan. When the European Commission launched an online public consultation on the Minamata Convention in 2014, fully 85% of the participating European public voted to "phase out" amalgam use in preference to "phase down" amalgam use.

### 2 Why dental amalgam use should be curtailed in the EU

Dental amalgam is a tooth filling material that is approximately 50% mercury, a neurotoxin that is recognized as a serious global contaminant. In addition, dental amalgam is regarded as an outdated material that is inconsistent with the tenets of modern dentistry (such as the principle of minimally invasive dentistry) and unnecessarily exposing patients and clinicians to environmental toxins. Along with governments in other parts of the world, many EU Member States are already working to phase down – and in some cases phase out – dental amalgam use, especially for the following reasons.

#### 2.1 Dental mercury pollution is significant

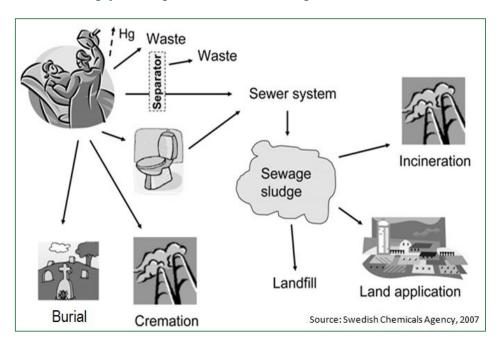
The European Parliament and the Council of the European Union have recognized that "*The use of mercury in dental amalgam is the largest use of mercury in the Union and a significant source of pollution.*"<sup>2</sup> A United Nations Environment Programme report found that mercury in dental use accounted globally for 226-322 metric tons in 2015. This represents 7-8% of global mercury consumption overall, and some 20% of global mercury consumption in products. It also shows that, per capita, the European Union is the largest regional user of dental mercury in the world – consuming 44-67 metric tons in 2015.<sup>3</sup> As the table below shows, most other regions consume significantly less dental mercury.<sup>4</sup>

Table 17. Mean mercury consumed by region and by major application, 2015										
Region	ASGM	VCM production	Chlor-alkali production	Batteries	Dental applications	Measuring and control devices	Lamps	Electrical and electronic devices	Hg compounds and other applications <sup>2</sup>	Regional totals
	mean <sup>3</sup>	mean <sup>3</sup>	mean <sup>3</sup>	mean <sup>3</sup>	mean <sup>3</sup>	mean <sup>3</sup>	mean <sup>3</sup>	mean <sup>3</sup>	mean <sup>3</sup>	mean <sup>3</sup>
East and Southeast Asia	645	1 215	8	95	52	208	69	52	62	2 407
South Asia	4	5	27	33	72	39	12	12	59	263
European Union (28 countries)	0	0	85	8	56	3	13	1	84	249
CIS and other Europe- an countries	24	6	45	13	19	12	7	7	37	171
Middle Eastern States	0	0	38	13	13	18	7	9	9	107
North Africa	0	0	11	8	4	6	4	2	5	41
Sub-Saharan Africa	366	0	1	24	7	11	5	19	15	447
North America	0	0	8	9	32	2	8	19	61	137
Central America and the Caribbean	16	0	19	9	6	9	4	6	8	78
South America	680	0	35	18	12	20	9	8	13	794
Australia, New Zealand and Oceania	0	0	0	1	3	1	3	13	1	22
Total per application	1 735	1 226	277	231	274	330	142	147	354	4 715

Approximately 370 million dental restorations were estimated to have been carried out in the European Union in 2010. Of that total, about one-third were done using dental amalgam (DG ENV 2012), although that fraction has declined since that research was published.

The World Health Organization (WHO) confirmed that "[a] significant amount of mercury is estimated to be released to the environment from the use of dental amalgam," according to the 2011 WHO report Future Use of Materials for Dental Restoration.<sup>5</sup> Dental mercury enters the three main environmental media via many different pathways. For example, dental mercury pollutes:

- AIR via cremation,<sup>6</sup> dental clinic emissions,<sup>7</sup> municipal waste incineration, and sewage sludge incineration<sup>8</sup>
- WATER via dental clinic releases,<sup>9</sup> landfill runoff and human waste<sup>10</sup>
- LAND via landfills,<sup>11</sup> burials,<sup>12</sup> and sewage sludge used as fertilizer.<sup>13</sup>



#### The many pathways of dental mercury into the environment

After mercury enters the environment, the European Commission's Scientific Committee on Health and Environmental Risks (SCHER) has confirmed that certain microorganisms can convert it into methylmercury, a highly toxic form of mercury that builds up in fish, shellfish, and people/animals/birds that eat fish. As a result *"the acceptable level [of mercury] in fish is exceeded"* sometimes in certain fish, and among the EU population consuming those fish there is *"a risk for secondary poisoning due to methylation."*<sup>14</sup> This secondary methylmercury poisoning can damage children's developing brains and nervous systems even before they are born.<sup>15</sup>

#### 2.2 Mercury-free dental fillings are available, effective, and affordable

Mercury-free dental fillings have been developed and studied for over fifty years.<sup>16</sup> With technological advances over the past decade, the cost of mercury-free fillings has continued to decline while their performance has improved. Furthermore, appropriate training permits dental practitioners to place mercury-free restorations as rapidly, on average, as amalgam. As a result, a wide variety – such as composites, compomers and glass ionomers<sup>17</sup> – are in widespread use today. These mercury-free fillings offer many advantages that make them more effective – and more affordable – than dental amalgam, as summarized in the table below.

	Environment- friendly	Preserve tooth structure	Releases Fluoride	Easier repairs	More accessible	Efficient to place	Filling longevity
Composite	✓	✓		✓		$\checkmark$	$\checkmark$
Glass ionomer	$\checkmark$	$\checkmark$	$\checkmark$		$\checkmark$	$\checkmark$	
Amalgam						$\checkmark$	$\checkmark$

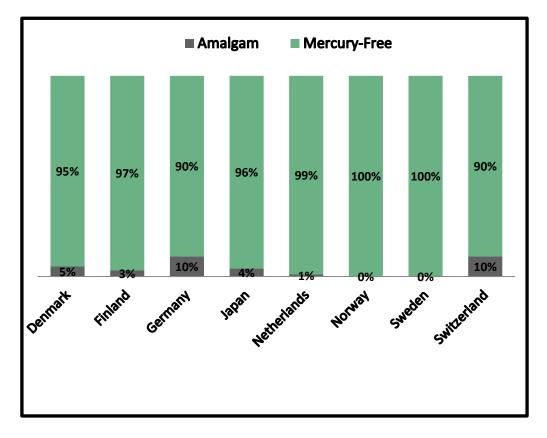
• Environment-friendly: Composites and glass ionomers are mercury-free, and there is no evidence of environmental toxicity.<sup>18</sup> However, as Swedish professor Hylander *et. al.* (2006) observes, "*amalgam fillings are considered to be economic while they de facto are more expensive than most, possibly all, other fillings when including environmental costs.*"<sup>19</sup> Hence,

Member States can avoid significant environmental and societal costs by promoting the use of mercury-free fillings.

- Preserve the tooth structure: Modern dentistry recognizes the principle of minimally invasive dentistry, which is basically the removal of the least possible amount of healthy tooth tissue. Contrary to this, the need for dental amalgam to be mechanically anchored in the tooth requires the drilling of an appropriate hole and the removal of often substantial healthy tooth tissue, consequentially leading to additional and more expensive repairs over time.<sup>20</sup> The World Health Organization states that "Adhesive resin materials [like composite] allow for less tooth destruction and, as a result, a longer survival of the tooth itself."<sup>21</sup> In addition to preserving tooth structure, due to their binding properties composites can strengthen and enhance the biomechanical properties of the restored tooth.<sup>22</sup> As the European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) stated in a 2015 report: mercury-free dental fillings "have facilitated a radical change in the concept of restorative dentistry through the introduction of more minimally invasive techniques and the associated retention of more tooth substance when treating caries."<sup>23</sup> Hence, Member States can save their citizens the added costs associated with weakened tooth structure and lost teeth by promoting mercury-free fillings.
- **Prevent caries:** Glass ionomers release fluoride, which might help prevent tooth decay.<sup>24</sup> Composite placement also can also incorporate preventive measures, including sealing of adjacent pits and tooth fissures.<sup>25</sup> Hence, mercury-free fillings maintain or exceed the preventive properties associated with amalgam.
- **Easier repairs:** Composite filling materials permit localized repairs whereas amalgam requires replacement of the total filling. Opdam *et. al.* found that composites are also typically repaired more successfully than amalgam, explaining that *"The annual failure rate (AFR) after 4 years for repairs of amalgam restorations was 9.3%, while the AFR of repaired composite restorations was 5.7%."*<sup>26</sup> Hence, Member States can save when it comes to filling repairs.
- **More accessible:** Glass ionomers, though less durable than composites or amalgam, have proven invaluable in clinical situations where they can be more accessible (easily placed in more humid environments) and less expensive than amalgam (for example, for treating children's milk teeth).<sup>27</sup> According to the BIOIS report for the European Commission, *"In Sweden, ART [atraumatic restorative treatment, a technique using glass ionomer] is used in public clinics and is considered as the treatment of choice for primary teeth."*<sup>28</sup> (As noted in the report, "With regard to young children, longevity of the restoration is not a relevant concern since baby teeth will fall out long before the restoration fails."<sup>29</sup>) The Pan American Health Organization further explains, *"The costs of employing the PRAT [procedures for atraumatic restorative treatment] approach [using glass ionomers] for dental caries treatment, including retreatment, are roughly half the cost of amalgam without retreatment. PRAT [using glass ionomer] as a best practice model provides a framework to implement oral health services on a large scale, and it can reduce the inequities for access to care services."<sup>30</sup> Hence, Member States can save considerable costs by using glass ionomer when appropriate.*
- Efficient to place: According to a 2012 report prepared for the European Commission, *"it has been shown that the time needed to carry out a Hg-free [mercury-free] restoration has reduced significantly as dentists have gained more experience in the handling of Hg-free materials, so that there is currently no (or minor) time difference to perform Hg-free restorations compared to amalgam."*<sup>31</sup> Optimized restorative composites can now save even more time even when dealing with bigger cavities (these bulk-fill composites can be placed and cured up to 4 mm deep and deliver strength and low wear for good durability).<sup>32</sup> Hence, once dentists are adequately trained, on average there are no additional labor costs associated with placing mercury-free fillings.
- Longevity: As the 2012 BIOIS report explained, "Given the results of recent studies comparing the longevity of different materials, in the present study it is considered that the longevity of Hgfree fillings is no longer a factor with significant effect on the overall cost difference between dental amalgam and composite or glass ionomer restorations."<sup>33</sup> A 2015 assessment by the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks

(SCENIHR) further confirmed that "dental restorative treatment can be adequately ensured by amalgam and alternative types of restorative material. The longevity of restorations of alternative materials in posterior teeth has improved with the continuing development of these materials and the practitioner's familiarity with effective placement techniques. ... recent studies from the Netherlands, Sweden and Denmark showed very good long-term clinical effectiveness for posterior resin composite restorations with equal and better longevity than for amalgam."<sup>34</sup> Hence, mercury-free filling materials such as composites are associated with no additional costs related to the longevity of the material.

Because mercury-free dental fillings are already effective and affordable, and these restoration materials continue to improve in any case, a growing number of countries (including many EU Member States) have already made significant progress in phasing down – as well as phasing out – dental amalgam use, as the below graphic shows already since 2012.<sup>35</sup>



#### Percentage (%) of amalgam versus mercury-free fillings placed<sup>36</sup>

## 2.3 The Minamata Convention on Mercury requires reductions in dental amalgam use

The Minamata Convention on Mercury, which entered into force in August 2017, is a global treaty to protect human health and the environment from the adverse effects of mercury. Coordinated implementation of the Convention's provisions will lead to a marked reduction in mercury levels in the environment over time. Among other provisions, the Convention requires each Party to "*phase down the use of dental amalgam.*" It addresses amalgam in Annex A, where it can be amended later to include a phase-out date.<sup>37</sup> The European Union ratified the Minamata Convention in May 2017, shortly after adopting the EU Mercury Regulation, which implements all of the provisions of the Minamata Convention (as relevant), and more.

### 3 Key measures to phase down dental amalgam use

The Minamata Convention lists measures to phase down amalgam use and instructs countries to undertake two or more of these measures. As country-level experiences in the European Union and elsewhere have shown, some measures are more effective and easier to implement than others. The table below presents four proven and effective phase-down measures that correspond to five pertinent provisions of the Minamata Convention and can be readily incorporated into Member States' national plans.

Proven Phase-Down Measure	Minamata Convention Measure Implemented
1. Set national objectives for minimizing amalgam use	Setting national objectives aimed at minimizing the use of dental amalgam (Annex A, Part II, ii)
2. Promote mercury-free dental fillings, including raising public awareness of the impacts of the mercury in amalgam	Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental restoration (Annex A, Part II, iii) Each Party shall, within its capabilities, promote and facilitateprovision to the public of available information onthe topics identified in paragraph 1 of Article 17 (including information on technically and economically viable alternatives to mercury-added products) (Article 18)
3. Update continuing education and dental school curricula to train dental professionals in mercury- free dentistry	Encouraging representative professional organizations and dental schools to educate and train dental professionals and students on the use of mercury-free dental restoration alternatives and on promoting best management practices (Annex A, Part II, v)
4. Modify insurance schemes and government programs to favor mercury-free dentistry, while eliminating subsidies for dental amalgam	Discouraging insurance policies and programs that favor dental amalgam use over mercury-free dental restoration (Annex A, Part II, vi) Encouraging insurance policies and programs that favor the use of quality alternatives to dental amalgam for dental restoration (Annex A, Part II, vii)

#### Incorporating phase-down measures into national plans

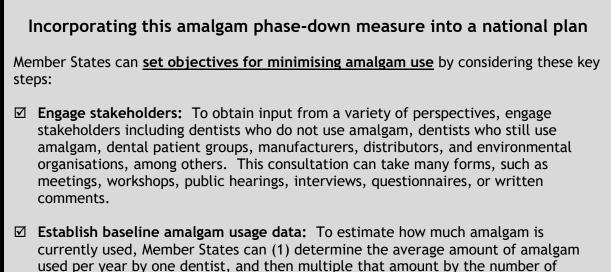
Implementing these dental amalgam phase-down measures in a cost-effective manner is explained in more detail in the following pages, along with pertinent examples from countries that have succeeded in phasing down or phasing out dental amalgam use.

#### 3.1 Set national objectives for minimising amalgam use

Establishing national objectives is an important step many countries have taken to phase down or phase out amalgam use. For example:

• Sweden: The government first announced its goal to phase out amalgam use. Then as Sweden progressed toward this goal, the objectives and strategies used to achieve it were refined with input from stakeholders – including a large number of companies, industry and trade associations, research institutes, non-governmental organizations (NGOs), and public authorities. They were reached via questionnaires, individual contacts, meetings, and study visits, as well as provided the opportunity to comment on a draft report of the findings.<sup>38</sup> Sweden phased out amalgam use in children and young people in 2009 and phased out all amalgam use by 2012.<sup>39</sup>

- **Finland:** After consultation with an expert group in 1993, Finland issued recommendations, including: (1) the use of dental amalgam should be reduced for environmental reasons; and (2) dental amalgam should be used only when other dental filling materials cannot be used. Since 1994, Finland's national guidelines stipulated that amalgam should not be used in restorations. The use of amalgam has declined significantly, recently accounting for no more than 3% of dental restorations.<sup>40</sup>
- Netherlands: After consultation with the dental sector, a major shift away from dental amalgam occurred in the 1990s. Subsequently, the average use of amalgam dropped from around 7% of all dental restorative fillings to less than 1% by 2011.<sup>41</sup>
- **Norway:** Before completely phasing out dental amalgam use, Norway developed guidelines stipulating that when a dental filling is placed, the technique used should involve the least possible amount of healthy tooth tissue removal. These guidelines focused on the crucial point that amalgam requires the removal of more healthy tooth tissue than mercury-free fillings. Hence, the guidelines encouraged the use of mercury-free fillings.<sup>42</sup>



- used per year by one dentist, and then multiple that amount by the number of dentists in the nation using amalgam, (2) require amalgam manufacturers or distributors to report how much amalgam they sell in the nation annually, and/or (3) track imports of encapsulated dental amalgam for use by the profession.
- ✓ Set goals: To ensure steady progress, Member States can set both long-term goals and short-term goals. For example, the long-term goal could be to phase out amalgam use completely, but a short-term goal might be to reduce amalgam use by 25% each year or end its use in government-supported clinics.
- Develop guidelines: To achieve their goals, Member States can set guidelines for when dental amalgam can be used - and when it cannot. For example, a Member State could prohibit amalgam use in all women of childbearing age and children up the age of 18, or prohibit use in the first treatment of a tooth.
- Announce goals and guidelines: To increase cooperation and support from stakeholders, nations can publicly announce (via press releases and other strategies) their commitment to minimising amalgam use.

- ☑ End trade in dental amalgam: Customs agencies should adopt enhanced Harmonized System (HS) Codes that enable identification of dental amalgam in order to track and/or disallow imports and exports.
- ☑ Stop amalgam donations: While well intended, international donor agencies that continue to provide support to programs using dental amalgam should change their guidelines.
- ☑ **Fix and announce a date to end all amalgam use:** Many Member States have already made significant progress in phasing down amalgam use. To take the next step, these Member States could announce a date by which all amalgam use in the country should end.
- ☑ **Track progress:** To determine amalgam use reductions over time, it is important to continue tracking the amount of amalgam used at regular intervals.

## 3.2 Promote mercury-free dental fillings, especially by raising public awareness of the impacts of mercury in amalgam

Experience by EU Member States clearly shows that raising public awareness about amalgam's mercury content and mercury-free dental fillings can phase down amalgam use. Already the European public that is aware of dental amalgam's mercury, strongly supports ending its use. When the European Commission launched an online public consultation on the Minamata Convention in 2014, 85% of those participating voted for a "phase out" of dental amalgam over a "phase down".<sup>43</sup>

Countries that phased down or phased out amalgam use cite high public awareness as an important factor in their success. For example:

- **Sweden:** The Swedish Chemicals Agency (KEMI) named "*High awareness of the environmental and health risks of mercury among patients*" as one of the "*most important explanations*" for that nation's ability to phase out amalgam use.<sup>44</sup>
- **Denmark:** In Denmark, the government explains "patients ask for alternatives due to public awareness."<sup>45</sup>
- **Norway:** A report for Norway's Climate and Pollution Agency explains, "The substitution of dental amalgam started as a result of public awareness and guidelines from the health authorities before the general ban on mercury in products was introduced by the environmental authorities."<sup>46</sup>

#### Incorporating this amalgam phase-down measure into a national plan

Member States can <u>raise public awareness</u> about the mercury in amalgam and <u>promote mercury-free dental fillings</u> with a variety of low-cost communication strategies,\* such as:

- Mass media: Conduct outreach through press releases, television, radio, and news articles.
- **Brochures:** Distribute brochures to patients at dental clinics and government-run healthcare facilities.
- ☑ **Consent forms:** Require dentists to obtain a patient signature on a consent form before placing amalgam.
- ☑ Posters: Develop posters or signs promoting mercury-free dentistry and post them at dental clinics and government-run healthcare facilities where the public can see them.
- ☑ **Online:** Provide more detailed information for the public on government websites.

\*Whatever communication strategy a Member State chooses, it is important to convey these basic facts: (1) amalgam is approximately 50% mercury; (2) mercury can have significant negative effects on human health and the environment; (3) the European Union and the Minamata Convention on Mercury require the phase-down of amalgam use; and (4) patients should ask for mercury-free dental fillings.

## 3.3 Update continuing education and dental school curricula to train dental professionals in mercury-free dentistry

Updating dental school curricula can help phase down amalgam use. Many dental schools still teach amalgam first and then provide instruction on mercury-free dental restorations later. Consequently, many dentists tend to use amalgam as a first choice, especially in posterior teeth (back teeth). As a 2011 study explains, "The risk in providing instruction in amalgam placement techniques before posterior resin-based composite placement techniques is that students base their approach to operative dentistry on outdated principles."<sup>47</sup> However, in countries where dental schools give preference to mercury-free dental restorations, amalgam use has more rapidly been phased down or phased out.

Health authorities in the European Union and elsewhere have worked collaboratively with dental schools to reduce amalgam use. For example:

- **Netherlands:** Dental schools in the Netherlands stopped instruction on the placement of dental amalgam use between 1995 and 2005.<sup>48</sup>
- **Sweden:** By the early 2000s, dental schools in Sweden provided instruction mainly on mercuryfree fillings, while amalgam instruction was only a small – and mostly theoretical – part of the training. For several years prior to its ban, amalgam placement was no longer taught.<sup>49</sup>

- **Denmark:** Dental schools in Denmark actively collaborated in amalgam phase-down efforts. Use of mercury-free alternatives was an integral part of each dental school's obligatory training.
- Japan: 93% of dental schools in Japan are reported to teach the use of mercury-free dental restorations in preference to amalgam.<sup>50</sup>

Incorporating this amalgam phase-down measure into a national plan
Member States can direct continuing education programs and dental schools - especially government-funded dental schools - to <u>update their curricula</u> by instructing them to implement the following steps:
☑ Inform current and future dentists about dental amalgam's impact on the environment, including how amalgam is a major source of mercury pollution in the air, water, and land.
Explain the benefits of using mercury-free dental fillings, including how they preserve tooth structure consistent with the principles of minimally-invasive dentistry, and reduce environmental and health impacts.
Encourage dental schools to design new teaching models that highlight the basic principles of minimally invasive dentistry.
☑ Emphasise training in the use of mercury-free dental restorations and techniques.
☑ <b>Require</b> competency exams only for mercury-free dental restorations.
Stop funding the purchase of dental amalgam for training purposes in dental schools.
☑ Set a deadline to end amalgam use in dental school clinics.
☑ Establish a date to end amalgam instruction in the classroom.

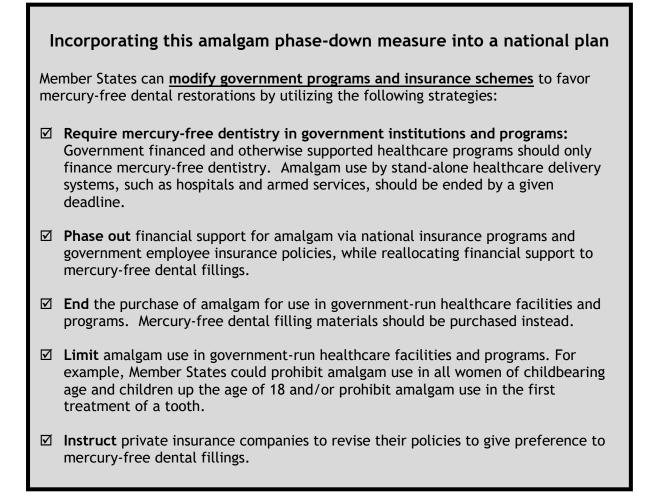
## 3.4 Modify insurance schemes and government programs to support mercury-free dentistry, while eliminating subsidies for dental amalgam

Modifying government programs and insurance schemes to favor mercury-free dentistry has been proven to help phase down amalgam use. "*Many insurance companies have traditionally only covered the cost of amalgam fillings, for marginal price reasons,*" according to an advisory note from the United Nations Environmental Programme. "*However, the full long-term environmental cost burden is not reflected in these price differences.*"<sup>51</sup>

As stated in the WHO report, *Future Use of Materials for Dental Restoration*, "existing or planned third-party payment systems must consider reimbursement schemes incorporating dental care which make use of materials alternative to dental amalgam."<sup>52</sup> Many countries that phased down or phased

out amalgam use included measures to modify government programs and insurance schemes. For example:

- **Sweden:** In 1999, the Swedish Parliament decided that no financial support should be given for amalgam via the national dental insurance scheme.<sup>53</sup> In fact, Sweden lists its "*decision to stop financial support for amalgam fillings from the national dental insurance service*" as among the "*most important explanations*" for ending the use of amalgam (Kemi 2011). The result was that the cost to the patient of an amalgam filling equaled or exceeded the cost of a composite filling. Unsurprisingly, when insurance reimbursement for amalgam was eliminated, its use dropped substantially.
- Mongolia: In 2011, the government ordered a ban on further procurement of amalgam and authorized directors of city and provincial healthcare departments and managers of healthcare facilities to take measures to reduce amalgam use and replace it with mercury-free alternatives.<sup>54</sup>



### 4 Summary

By 1 July 2019, EU Member States have agreed to develop plans to phase down the use of dental amalgam. Fortunately, a number of Member States have already paved the way through their experiences in successfully phasing down, and in several countries completely phasing out dental amalgam use.

This document provides a menu of proven measures that countries may consider for incorporation into their national plans. The main amalgam phase-down measures include:

- Setting national objectives for minimising dental amalgam use
- Promoting mercury-free dental fillings, including raising public awareness of the impacts of the mercury in amalgam
- Updating continuing education and dental school curricula to prioritize and train dental professionals in mercury-free dentistry
- Modifying insurance schemes and government programs to encourage mercury-free dentistry, while phasing out subsidies for dental amalgam

For Member States to avoid the extended social and economic costs and impacts of dental mercury pollution, coherent national plans are needed that will also contribute to the Minamata Convention's objective *"to protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds"*. Clearly, the most sustainable long-term and cost effective solution for Member States is to effectively phase down – with the intention to ultimately phase out – dental amalgam use in a timely manner.

Your NGO partners stand ready to assist as appropriate.

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<sup>6</sup> OSPAR Commission, Overview assessment of implementation reports on OSPAR Recommendation 2003/4 on controlling the dispersal of mercury from crematoria (2011)

<sup>7</sup> See KA Ritchie et. al., Mercury vapour levels in dental practices and body mercury levels of dentists and controls, BRITISH DENTAL JOURNAL Volume 197 No. 10 November 27 2004, http://www.nature.com/bdj/journal/v197/n10/pdf/4811831a.pdf ("One hundred and twenty two (67.8%) of the 180 surgeries visited had environmental mercury measurements in one or more areas above the Occupational Exposure Standard (OES) set by the Health and Safety Executive."); see also Mark E. Stone, Mark E. Cohen, Brad A. Debban, *Mercury vapor levels in exhaust air from dental vacuum systems*, Dental Materials 23 (2007) 527–532.

<sup>8</sup> U.S. Geological Survey, *Changing Patterns in the Use, Recycling, and Material Substitution of Mercury in the United States* (2013), p.23

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<sup>14</sup> SCHER, *Opinion on Environmental Risks and Indirect Health Effects of Mercury from Dental Amalgam* (2014), http://ec.europa.eu/health/scientific\_committees/environmental\_risks/docs/scher\_o\_165.pdf, page 4

<sup>15</sup> U.S. EPA, EPA Will Propose Rule to Protect Waterways by Reducing Mercury from Dental Offices (2010).

<sup>16</sup> Jack L Ferracane, Resin composite--state of the art, DENTAL MATERIALS, Vol.27, issue 1, p.29-38 (Jan. 2011).

<sup>17</sup> Modern glass ionomer restoratives are strong, radiopaque, for long-term Class I (one surface) and Class II (multiple surfaces) restorations with restrictions. They are available in both capsule or hand mix format and are used as a bulk placed restorative. Modern glass ionomers provide an excellent seal on the margins of fillings and can be applied without the need of a liner, cavity conditioner or final glaze for protection. See 3M, Alternatives to Amalgam (2018), Indications for use: 1. Stress-bearing Class I restorations with at least one additional support outside of the filling area; 2. Stress-bearing Class II restorations when the isthmus is less than half of the intercuspal distance and with at least one additional support outside of the filling area https://multimedia.3m.com/mws/media/1572045O/alternatives-to-amalgam.pdf

<sup>18</sup> Health Care Research Collaborative of the University of Illinois at Chicago School of Public Health, the Healthier Hospitals Initiative, and Health Care Without Harm, *Mercury in Dental Amalgam and Resin-Based Alternatives: A Comparative Health Risk Evaluation* (June 2012), p.6.

 <sup>19</sup> Lars D. Hylander & Michael E. Goodsite, Environmental Costs of Mercury Pollution, Science of the Total Environment 368 (2006) 352-370, http://www.aikencolon.com/assets/images/pdfs/Nikro/MercuryVacuum/STOTENbestpaper.pdf
<sup>20</sup> DHSA (2003) – A National Clinical Guideline for the Use of Dental Filling Materials, Department for Municipal Health and

Social Services, Directorate for Health and Social Affairs, Universitesgata 2, Oslo,Norway, ISBN 82-8081-031, December 2003, <sup>21</sup> World Health Organization, *Future Use of Materials for Dental Restoration* (2011), p.16.

<sup>22</sup> Lynch et. al., Managing the phase-down of amalgam: part I. Educational and training issues, BR DENT J. (Aug. 2013).
<sup>23</sup> European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users (29 April 2015),

http://ec.europa.eu/health/scientific\_committees/emerging/docs/scenihr\_o\_046.pdf, p.69

<sup>24</sup>Mandari GJ, Mandari GJ, Frencken JE, Frencken JE, van't Hof MA, *Six-Year Success Rates of Occlusal Amalgam and Glass-*Ionomer Restorations Placed Using Three Minimal Intervention Approaches. CARIES RES 2003;37:246-253.

<sup>25</sup> Lynch et. al., Managing the phase-down of amalgam: part I. Educational and training issues, BR DENT J. (Aug. 2013).

<sup>26</sup> Opdam NJ, Bronkhorst EM, Loomans BA, Huysmans MC, Longevity of repaired restorations: A practice based study, Journal of Dentistry 40 (2012) 829–835 states, "The annual failure rate (AFR) after 4 years for repairs of amalgam restorations was 9.3%, while the AFR of repaired composite restorations was 5.7%. The log-rank test revealed a significantly superior performance of repairs of composite restorations (p = 0.001)... The results of the study as shown in Fig. 4 and the log-rank test

indicating high significance suggest that a composite restoration can be repaired more successfully than an amalgam restoration." The reason was that "In the present study it was found that repaired restorations in case of tooth fracture, which is a common failure type among large amalgam restorations, have a worse prognosis then repaired restorations due to recurrent caries, which is more common among the composite resin restorations investigated. [As explained,] a repaired restoration in case of e.g. a cusp fracture (Fig. 2) will be subjected to the same forces that caused the same cusp fracture, leading to a second fracture soon. On the other hand, a secondary caries lesion in a large composite resin restoration that is repaired with a local box-type restoration (Fig. 3) is likely to survive longer due to the fact that a new secondary caries lesion needs at least three years to develop to a size making a new operative intervention necessary. Moreover, preventive measures taken may cause the demise of caries activity in the patient preventing new secondary caries lesions to develop." See https://www.researchgate.net/profile

/Niek\_Opdam/publication/228441700\_Longevity\_of\_repaired\_restorations\_A\_practice\_based\_study/links/0c96052766a325245 a000000.pdf

<sup>27</sup> Pan American Health Organization, Oral Health of Low Income Children: Procedures for Atraumatic Restorative Treatment (PRAT) (2006), p.xi.

<sup>&</sup>lt;sup>1</sup> Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (Text with EEA relevance)

<sup>&</sup>lt;sup>2</sup> Ibid.

<sup>&</sup>lt;sup>4</sup> Ibid., p.62

<sup>&</sup>lt;sup>5</sup> World Health Organization, Future Use of Materials for Dental Restoration (2011), p.13.

<sup>28</sup> BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV, p.56.

<sup>29</sup> BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV,

http://ec.europa.eu/environment/chemicals/mercury/pdf/Final\_report\_11.07.12.pdf, p.69

<sup>30</sup> Pan American Health Organization, Oral Health of Low Income Children: Procedures for Atraumatic Restorative Treatment (PRAT) (2006), http://new.paho.org/hq/dmdocuments/2009/OH\_top\_PT\_low06.pdf, p.xi.

<sup>31</sup>BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV, p.67.

<sup>32</sup> Bulk fill restoratives are visible-light activated, restorative composites optimized to create fast and easy restorations and provide excellent strength and low wear for durability. The material can be placed and cured up to 4 mm deep, enabled by a stress-relieving resin system and optimized optical properties. "Dentists get composite restorative materials with strong physical properties which guarantee a permanent yet economical solution. It can be cured within 10 seconds." See VOCO, Three alternatives to amalgam fillings (2018) at https://www.voco.dental/en/service/press/press-area/three-alternatives-to-amalgamfillings.aspx

<sup>33</sup> BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV,

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<sup>34</sup> European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users (29 April 2015), http://ec.europa.eu/health/scientific\_committees/emerging/docs/scenihr\_o\_046.pdf, p.8,10,77

<sup>35</sup> BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV, p.190, Bio Intelligence Service/European Commission, Review of the Community Strategy Concerning Mercury (p.213-14), 4 October 2010; Federal Office for the Environment (Switzerland), Letter (8 August 2011); World Health Organization, Future Use of Materials for Dental Restoration (2011), pp.21, 23; UNEP, Lessons from Countries Phasing Down Dental Amalgam Use (2016), p.13.

<sup>36</sup> BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV, p.190; Bio Intelligence Service/European Commission, Review of the Community Strategy Concerning Mercury (p.213-14), 4 October 2010; Federal Office for the Environment (Switzerland), Letter (8 August 2011); World Health Organization, Future Use of Materials for Dental Restoration (2011), pp.21, 23; UNEP, Lessons from Countries Phasing Down Dental Amalgam Use (2016), p.13.

Minamata Convention (2013) (emphasis added).

<sup>38</sup> Swedish Chemicals Agency, Mercury-investigation of a general ban, Report, No 4/04 (2004), pp.7, 14, 31.

<sup>39</sup> BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV, p.58.

<sup>40</sup> UNEP, Lessons from Countries Phasing Down Dental Amalgam Use (2016), p.12

<sup>41</sup> UNEP, Lessons from Countries Phasing Down Dental Amalgam Use (2016), p.13

<sup>42</sup> UNEP, Lessons from Countries Phasing Down Dental Amalgam Use (2016), p.24

<sup>43</sup> EU Survey, Published Results: Minamata Convention, https://ec.europa.eu/eusurvey/publication/MinamataConvention#

<sup>44</sup> Swedish Chemicals Agency, Mercury Phase-Out: A Study of the Experiences of Swedish Companies (October 2011), p.15. <sup>45</sup> Request for Information of Mercury in Products and Processes, Quantities Used, Demand, Level of Substitution, Technology Change-over, Available Substitutes, submission to UNEP (2010).

<sup>46</sup> Climate and Pollution Agency, Review of Norwegian experiences with the phase-out of dental amalgam use (2012), p.6.

<sup>47</sup> Christopher D. Lynch, Kevin B. Frazier, Robert J. McConnell, Igor R. Blum and Nairn H.F. Wilson, *Minimally invasive* management of dental caries: Contemporary teaching of posterior resin-based composite placement in U.S. and Canadian dental schools, J AM DENTA ASSOC 2011; 142; 612-620.

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<sup>52</sup> World Health Organization, Future Use of Materials for Dental Restoration (2011), p.36.

<sup>53</sup> Swedish Chemical Agency, Mercury-free Dental Fillings: Phase-out of amalgam in Sweden (2005).

<sup>54</sup> Joint Order of the Minister of Health and General Director of the National Emergency Management Agency of Mongolia, No.07/27 (11 Jan. 2011).