

## HCWH Europe Position Paper on Proposed Mercury Regulation July 2016

### Background information

On 2<sup>nd</sup> February 2016, the European Commission proposed a new regulation on mercury (the Proposal<sup>1</sup>), which will repeal Regulation (EC) No 1102/2008 of the European Parliament and the Council of 22<sup>nd</sup> October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury.

The Proposal seeks to align EU law with the provisions of the International Convention on Mercury (Minamata Convention). The United Nations Environment Programme initiated the negotiations of the Minamata Convention in 2009. The Minamata Convention was signed in 2013 and 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 Proposal focuses on gaps that exist in EU legislation for it to be compliant with the Minamata Convention. These are:

- 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

### Introduction

For many years HCWH Europe has advocated the adoption and implementation of legally binding instruments that would reduce mercury pollution globally - to protect the environment and human health. HCWH Europe has worked on the phase out of mercury-based thermometers (achieved in 2007), and mercury based blood pressure devices (achieved in 2012), and the Minamata convention (agreed in 2013). Mercury free healthcare is at the core of Health Care Without Harm's work - based on the Hippocratic Oath: First do no harm. The United Nations Environment Programme (UNEP) and World Health Organization (WHO) identified the adverse effects of mercury pollution as a serious global environmental and human health problem. HCWH and the WHO collaborated on mercury free healthcare in 2008, aimed at demonstrating the feasibility of phasing out of mercury-based thermometers and sphygmomanometers in health care and substituting them with accurate and economically viable alternatives. We are concerned by the adverse effects of mercury pollution, and whilst we welcome the European Commission's Proposal - we deplore its modest level of ambition.

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<sup>1</sup> COM (2016) 39 final Proposal for a Regulation of the European Parliament and of the Council on mercury, and repealing Regulation (EC) No 1102/2008, 2 February 2016

HCWH Europe's members are hospitals, healthcare systems, and healthcare professionals, and therefore our main focus is on Article 10 of the Proposal, which deals with dental amalgam. Dental amalgam is a combination of metals containing about 50% mercury in elemental form; other metals used are silver (35%), tin, copper, and other trace metals. Our specific concern with dental amalgam is that it contributes to the accumulation of mercury in the environment globally, since mercury does not degrade. Two thirds of mercury used in dental amalgam is released into the environment.<sup>2</sup>

Mercury is recognised as a global threat to the environment and human health, with the United Nations Environment Programme (UNEP) and the World Health Organization (WHO) listing mercury amongst the '*ten chemicals of major public health concern*'.<sup>3</sup> Exposure to mercury may result in harmful effects on the central nervous system, thyroid, kidneys, lungs, immune system, eyes, gums, and skin.<sup>4</sup>

HCWH Europe has further concerns related to the fact that mercury is transported in the atmosphere, as well as its persistence in the environment, toxicity, and its ability to bio-accumulate in ecosystems make it a real hazard for human and animal health. It is also well known that some types of bacteria and fungi can convert mercury into its most toxic form: methyl mercury, which accumulates in aquatic organisms e.g. fish and plants.

Dental amalgam fillings are the largest source of exposure to mercury for most people. According to the *Staff Working Document (SWD/2016/017)* of the European Commission, previous studies reported that the quantity of mercury contained in people's mouths in the 27 EU countries was estimated to be over 1,000 tonnes.<sup>5</sup>

In this same European Commission document, it is recalled that elemental mercury is a major component (approximately 50%) of dental amalgam in the form of an alloy that is solid at room temperature. They point at the fact that "*elemental mercury released into the mouth can be oxidised to inorganic mercury which may be transformed by bacteria to methylmercury after it is released into saliva*".

The document continues, stating that: "*after oral intake, methylmercury is much more extensively and rapidly absorbed than elemental or ionic mercury and accumulated in hair, the fetus, and the brain*". That is also why they warn that "*the benefits of fish in human nutrition should be kept in mind, eating mercury-contaminated fish can have significant negative health impacts in the long-run*".

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<sup>2</sup> UNEP (2016) Lessons from countries phasing down dental amalgam use, page 10

<sup>3</sup> [http://www.who.int/ipcs/assessment/public\\_health/chemicals\\_phc/en/](http://www.who.int/ipcs/assessment/public_health/chemicals_phc/en/)

<sup>4</sup> <http://www.who.int/mediacentre/factsheets/fs361/en/>

<sup>5</sup> SWD/2016/017 final - 2016/023 (COD) Commission Staff Working Document Ratification and Implementation by the EU of the Minamata Convention, pages 157

Still in the same document, but on controlling methylmercury in general, they refer to following:

*Recent research quantified the monetary benefits from control of methylmercury (MeHg) toxicity in the EU at between €8,000million - €9,000million per year. This estimate was calculated from research findings, on the basis of population biomarker data, that 1.5m - 2.0m EU children are born each year exceeding exposure limits associated with long term IQ deficits. Unfortunately, due to the complexity of the issue, there are currently no models available to quantify the link between anthropogenic mercury releases with human exposure. However, the long timescales of mercury cycling in the environment suggest that any anthropogenic mercury releases persist and can affect biological exposures for centuries to millennia.<sup>6</sup>*

The last section of this paper (General points on the Proposal) outlines our position on key provisions of the Draft Report of the European Parliament prepared by the ENVI Committee (*Draft Eck Report (2016)*)<sup>7</sup>. The Eck report will form the basis of the European Parliament's position in the legislative process that should lead to the adoption of the Mercury Regulation. The Annexes to this paper also provide some facts and figures about mercury in dental amalgam and its persistence in the environment.

## A. Dental Amalgam – Article 10 of the Proposal

As mercury will be phased out in the EU chlor-alkali industry (by 2017<sup>8</sup>), dental amalgam is expected to become the largest source of mercury in the EU, with current usage estimated at 75t/y.<sup>9</sup> According to the *European Commission Consultation (2014)*, 85.41% of respondents were in favour of a phase-out of dental amalgam<sup>10</sup>. This clear signal was ignored by the European Commission when drafting the Proposal, and is not reflected in the current proposal.

<sup>6</sup> Ibid, page 88. See also Bellanger M, Pichery C, Aerts D, Berglund M, Castano A, Cejchanova M, Crettaz P, Davidson F, Esteban M, Exley K, et al: *Economic benefits of methylmercury exposure control in Europe: Monetary value of neurotoxicity prevention*. Environ Health 2013, 12:3.

<sup>7</sup> COM (2016)0039 – C8-0021/2016 – 2016/0023(COD) – *Draft Report on the proposal for a regulation of the European Parliament and of the Council on mercury, and repealing Regulation (EC)*

<sup>8</sup> The phasing out of mercury technology in the Chlor-Alkali industry under the Industrial Emissions Directive (2010), through the BAT conclusions (Best Available Technology) have become legally binding. The national authorities had to 'reconsider permit conditions' and 'take into account the BAT conclusions', implying that four years after publication of these BAT conclusions, this means before 11 December 2017, mercury-based production technology must be ceased. See 2013/732/EU: Commission Implementing Decision of 9 December 2013: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013D0732>

<sup>9</sup> SWD/2016/017 final - 2016/023 (COD) Commission Staff Working Document Ratification and Implementation by the EU of the Minamata Convention, page 143

<sup>10</sup> European Commission (2014) *Public Consultation on the Ratification by the EU of the Minamata Convention on Mercury* [http://ec.europa.eu/environment/consultations/mercury\\_en.htm](http://ec.europa.eu/environment/consultations/mercury_en.htm)

## **ARTICLE 10 FAILS TO ADDRESS THE REQUIREMENTS OF THE MINAMATA CONVENTION**

Having disregarded the result of their own consultation, the European Commission proposed measures that show a lack of leadership and ambition. This is all the more disappointing given the role the European Commission played in the negotiation at global level leading up to the adoption of the Minamata Convention. The measures in the Proposal will not reduce the amount mercury present in the EU - at best, they will contain the releases of mercury into the environment, mitigating health concerns.

Out of the nine measures listed in the Minamata Convention to be taken by a Party to phase down the use of dental amalgam<sup>11</sup>, the parties must at least adopt two. Although free to adopt more, the Commission selected just two. In Article 10 of the Proposal, the Commission selected the following measures: (1) As of 1st January 2019, dental amalgam shall only be used in encapsulated form and, (2) dental facilities shall be equipped with amalgam separators to retain and collect amalgam residues.

As explained below, these measures will not translate into a reduction (i.e. a phase down) in the use of dental amalgam, as they are already largely in place in most EU member states and have been for quite some time.

## **THE MEASURES OUTLINED IN ARTICLE 10 ARE ALREADY IN PLACE IN MOST OF THE EU MEMBER STATES**

### **Dental amalgam in encapsulated form**

To put the level of ambition of the Commission into perspective, one should recall that a 2008 study for the Commission estimated that 70% of dental amalgam used in the EU in 2007 was already in encapsulated form.<sup>12</sup>

The *Staff Working Document (SWD/2016/017)* of the European Commission reported that a recent survey by the Council of European Dentists (CED), carried out in 26 European countries suggested that: “*in terms of use, seventeen European countries reported 100% use of pre-dosed capsules...*” (i.e. dental amalgam in encapsulated form), “*...another four reported very high percentages (65-95%), while another four provided no estimates*”.<sup>13</sup>

Based on the data in the *Staff Working Document (SWD/2016/017)*, we know that 17 member states already use pre-dosed capsules, and another 4 reported a high use of encapsulation. Combined with the fact that 2 EU member states (Denmark and Sweden) have banned the use of dental amalgam, and 2 more (The Netherlands and Finland) have virtually eliminated mercury from use in dentistry, we are left with just 3 EU member states that would be affected by this provision.

<sup>11</sup> Minamata Convention Text and Annexes (October 2013):  
[http://www.mercuryconvention.org/Portals/11/documents/Booklets/Minamata Convention on Mercury\\_booklet\\_English.pdf](http://www.mercuryconvention.org/Portals/11/documents/Booklets/Minamata%20Convention%20on%20Mercury_booklet_English.pdf)

<sup>12</sup> SWD/2016/017 final - 2016/023 (COD) Commission Staff Working Document Ratification and Implementation by the EU of the Minamata Convention, page 36

<sup>13</sup> Ibid, page 36

Given that mercury-free dental filling materials are used more often than dental amalgam in the EU (66% of restorations in 2012), the use of bulk mercury concerns a very small percentage (approximately 10%) of the total number of fillings, the *Staff Working Document (SWD/2016/017)* reported.

### Use of amalgam separators in the EU

As for amalgam separators, most dental practices are equipped with such filters aiming to minimise the quantity of mercury leaked into the sewage system. According to the *EU Manual of Dental Practice* (2015), published by the CED, 22 out of the 28 EU member states already have binding legislation requiring the use of amalgam separators.<sup>14</sup>

Clearly, the measures in the Proposal will not translate in a reduction in the use of dental amalgam, as mandated by the Convention. Given that most of the EU member states have already made amalgam separators mandatory, and that the use of dental amalgam in encapsulated form is widespread, the Proposal is little more than a cosmetic regulatory catch-up exercise maintaining the *status quo*.

## B. HCWH Europe recommendation

HCWH Europe therefore calls on the EU to adopt measures that will actually address the persistent concerns around dental amalgam. We support the phase-out of mercury in dentistry as proposed by the *Draft Eck Report (2016)*<sup>15</sup>, which proposes that:

- From 1<sup>st</sup> July 2017 onwards, dental amalgam in any form shall not be used for the treatment of pregnant and breastfeeding women and the primary teeth of children.
- From 1<sup>st</sup> January 2018 onwards, dental amalgam shall only be used in an encapsulated form.
- The use of dental amalgam shall be phased-out for all patients by 31<sup>st</sup> December 2021.

We believe that such a staggered plan is a sensible approach, as it would allow sufficient time for regular consultation with dental associations to address their concerns regarding such a phase-out.

Currently, there is a ban on the use of mercury in dentistry in Denmark and Sweden, and mercury has been virtually eliminated from use in Finland and the Netherlands.<sup>16</sup> The dental sector in these countries, though initially reticent, became actively involved and helped to achieve an efficient transition to alternatives.

<sup>14</sup> See **Annex I** for table with date of when national law was adopted. Council of European Dentists (2015) *EU Manual of Dental Practice*

<sup>15</sup> COM (2016)0039 – C8-0021/2016 – 2016/0023(COD) – *Draft Report on the proposal for a regulation of the European Parliament and of the Council on mercury, and repealing Regulation (EC)*

<sup>16</sup> UNEP (2016) *Lesson from countries phasing down dental amalgam use*

Importantly, it should also be noted that such a phase-out would have the merit of fitting with the better regulation agenda of the EU. Dental amalgam is a medical device, and under the Medical Devices Regulation (soon to be formally adopted), it will be necessary to show “*why possible substances and/or material substitutes or design changes, if available, are inappropriate to maintain the functionality, performance, and the benefit-risk ratios of the product*”.<sup>17</sup>

Annex I, point 7.4, of the Medical Devices Regulation actually mandates that carcinogenic, mutagenic, or reprotoxic (CMR) substances should be phased out if alternatives are available and viable - mercury is a CMR substance.<sup>18</sup> As mentioned under points C5 and C6 of this paper, there are alternatives to dental amalgam currently available, and this is obviously attested by the fact that 4 EU member states have virtually banned dental amalgam.<sup>19</sup>

In short, the modest approach of the Proposal mandating separators and encapsulation runs counter to the substitution route put forward in the Medical Devices Regulation. This will create confusion, send the wrong signal, and ultimately fail to address the negative environmental and health impacts of mercury used in dental amalgam. It is therefore imperative that the EU sets out a clear policy direction towards a non-toxic environment with respect to mercury in dental amalgam.

As the European Commission knows: “*more stringent regulations are likely to induce radical innovations, provided that the distance between regulatory requirements and the status quo is not excessive, and that the outcome is specified in a technology-neutral manner*”.<sup>20</sup>

## C. Specific considerations

### 1. ENVIRONMENTAL HAZARDS LINKED TO DENTAL AMALGAM

The environmental impact of mercury from dental amalgam has been considered by SCHER, a European Commission scientific committee. Though more research is needed, because “*For the soil and air compartment, a quantitative Predicted Environmental Concentration cannot be estimated and an assessment of local risk is not possible*”.<sup>21</sup> Yet SCHER did confirm that dental amalgam can methylate in the environment, creating the most toxic form of mercury: methylmercury, and the “*risk of secondary poisoning due to methylation cannot be excluded*”.<sup>22</sup>

<sup>17</sup> Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 page 208. The Medical Devices Regulation addresses, *inter alia*, the presence of Carcinogenic, Mutagenic and Reprotoxic substances (CMRs) and Endocrine Disrupting Chemicals (EDCs) contained in medical devices. Dental amalgam is considered a medical device.

<sup>18</sup> CMR substances from Annex VI of the CLP Regulation registered under REACH and/or notified under CLP -A first screening - Report 2012

<sup>19</sup> UNEP (2016) *Lesson from countries phasing down dental amalgam use*, pages 11-13

<sup>20</sup> Better Regulation Tool Box: [http://ec.europa.eu/smart-regulation/guidelines/docs/br\\_toolbox\\_en.pdf](http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf), page 122

<sup>21</sup> *Opinion on the environmental risks and indirect health effects of mercury from dental amalgam (update 2014)*, Scientific Committee on Health and Environmental Risks (SCHER), page 4

<sup>22</sup> *Ibid*, page 4. Secondary poisoning is when one organism comes into contact with or ingests another organism that has poison in its system.



The *Staff Working Document (SWD/2016/017)* of the European Commission, however, is filled with statements on mercury emissions from dental amalgam. It estimates that about half of the mercury released from current and historical dental amalgam use remains potentially bioavailable, with the potential to contaminate fish in particular.<sup>23</sup>

More recently, the UNEP reported that two thirds of dental mercury is released into the environment.<sup>24</sup> Clearly, managing amalgam waste with separators, amalgamators (a device used to mix mercury with the other alloys to produce the amalgam), and best management practices alone is not sufficient in itself to address the whole range of mercury releases from the life cycle of dental amalgam.<sup>25</sup>

## 2 – HEALTH HAZARDS LINKED TO DENTAL AMALGAM

Mercury is recognised as a global threat to the environment and human health - the United Nations Environment Programme (UNEP) and World Health Organisation (WHO) list mercury among the '*ten chemicals of major public health concern*'.<sup>26</sup> Exposure to mercury may result in harmful effects on the central nervous system, thyroid, kidneys, lungs, immune system, eyes, gums, and skin.<sup>27</sup>

SCENIHR, the European Commission's scientific committee, acknowledges the risks of dental amalgam in recommending "*that for the first treatment of primary teeth in children and for pregnant patients, alternative materials to amalgam should be the first choice*". It is unambiguous in stating that "*[t]he use of amalgam restoration is not indicated in primary teeth, in patients with mercury allergies, and persons with chronic kidney diseases with decreased renal clearance*".<sup>28</sup>

This acknowledgement appears to be somewhat overdue. In the report *The real cost of dental mercury (2012)*<sup>29</sup> the authors observe that "*the dental industry [...] has helped to make dental practitioners aware of the hazards. Encapsulated dental amalgam is typically shipped from manufacturers in packaging with a "skull and crossbones" symbol affixed next to the words: "Poison, contains metallic mercury." Amalgam manufacturers – Kerr, Vivadent, and Dentsply, among others – clearly for health reasons, consistently advise dentists against placing amalgam in the teeth of pregnant women, nursing mothers, children under six, and anyone with kidney disease*". Sadly, however, these warnings are generally not passed along to the public by the dental industry, the authors observed.

<sup>23</sup> SWD/2016/017 final - 2016/023 (COD) Commission Staff Working Document Ratification and Implementation by the EU of the Minamata Convention, page 144, 154.

<sup>24</sup> UNEP (2016) *Lessons from countries phasing down dental amalgam use*, page 10

<sup>25</sup> To get a graphic view of the environmental hazards caused by dental amalgam, consult **Annex II** of this paper. It shows that dental mercury is entering the environment via many pathways. It goes into the air via cremation, dental clinic emissions, sludge incineration, and respiration. Dental clinic releases and human waste end up in the water. The soil is also contaminated via landfills, burials, and fertiliser.

<sup>26</sup> [http://www.who.int/ipcs/assessment/public\\_health/chemicals\\_phc/en/](http://www.who.int/ipcs/assessment/public_health/chemicals_phc/en/)

<sup>27</sup> <http://www.who.int/mediacentre/factsheets/fs361/en/>

<sup>28</sup> *Opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users*, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), (2015), pages 75-76.

<sup>29</sup> Concorde (2012) *The real cost of dental amalgam*, page 6: [http://mercurypolicy.org/wp-content/uploads/2012/04/real\\_cost\\_of\\_dental\\_mercury\\_april\\_2012-final.pdf](http://mercurypolicy.org/wp-content/uploads/2012/04/real_cost_of_dental_mercury_april_2012-final.pdf)

Interestingly, those countries that have either banned or drastically phased down dental amalgam all started by issuing a recommendation against the use of amalgam for vulnerable populations such as children and pregnant women. For example, Norway and Sweden introduced step-by-step legislation that allowed time for the industry and for dentists to adapt to the new restrictions or guidelines.<sup>30</sup>

### 3 – ACTION PLAN

EU member states should develop an Action Plan to phase-out amalgam.<sup>31</sup> Whilst every EU member state should do so in a fashion that is appropriate to their own circumstances, there are essentially two ways to go about reducing mercury releases from dental amalgam: (1) source reduction (a phase-out) and (2) pollution management - which is what the BIOS Study, prepared for the European Commission's DG ENV, concluded in 2012.<sup>32</sup>

### 4 – INFORMING AND EDUCATING THE PUBLIC AND HEALTHCARE PROFESSIONALS

**Patients** – Patients should be informed about the dangers associated with dental amalgam. The minimum information to be provided by dentists should include that: (1) dental amalgam is a combination of metals containing about 50% mercury, (2) the recommendation of SCENIHR which states that the use of amalgam restoration is not recommended in primary teeth, in patients with mercury allergies, and persons with chronic kidney diseases, or with decreased renal clearance, and (3), mercury-free alternatives are available.

In the 2016 UNEP report, *Lessons from countries phasing down dental amalgam use*, we learn that in Norway just presenting the information on alternative dental restorative materials in a balanced manner resulted in a move away from amalgam before bans on dental amalgam were introduced. This was due to public awareness. In Sweden, for example, this awareness of both “*the environmental and health risks of mercury among patients*” is one of the “*most important explanations*” for the virtual elimination of amalgam use.<sup>33</sup>

**Professionals** – We believe that any measure adopted by the EU should consult the affected parties and involve them in the process. Information and education are crucial parts of this process. The UNEP *Lessons from countries phasing down dental amalgam use* report refers to a survey that showed the dental profession was neither aware of the environmental impacts of mercury from amalgam, nor of the social benefits of reducing mercury emissions. Those very countries that have introduced a virtual ban, or have drastically reduced the use of dental amalgam, have done so relying on modern and adapted higher education training.<sup>34</sup>

<sup>30</sup> UNEP (2016) *Lesson from countries phasing down dental amalgam use*, page 21

<sup>31</sup> On 2 June 2016, UNEP Deputy Regional Director Isabelle Louis was quoted in the *Dhaka Tribune* on the Bangladesh Action Plan to phase-down amalgam: “*The national and sub regional action plans are crystal clear, set specific timeline and it is inspirational,*” she added. “*It will eventually bring good for individual health and then certainly the whole nation.*” The EU should perhaps take a leaf out of their book and mandate such plans.

<sup>32</sup> European Commission (DG ENV), BIO Intelligence Service (BIOIS) (2012) *Study on the Potential for Reducing Mercury Pollution from Dental Amalgam and Batteries*, page 108

<sup>33</sup> UNEP (2016) *Lessons from countries phasing down dental amalgam use*, page 20

<sup>34</sup> Ibid, pages 18-19. In Sweden amalgam placement was not taught for several years prior to its ban. Dental schools have since demonstrated the efficacy of mercury-free alternatives. In Denmark dental schools are



## 5 – QUALITY OF ALTERNATIVES

The 2016 report *Global Dental Restorative Supplies Industry*<sup>35</sup>, confirms the move away from dental amalgam on account of consumer preferences and advances in composite materials. They note the growing popularity of all-ceramic restorations and the use of composite resin. The advances in composite materials are contrasted with the growing calls for a phase down of amalgam.<sup>36</sup> These trends corroborate the findings of a series of earlier reports and studies from international bodies that have changed the nature of the discussion on the quality and safety of alternatives versus dental amalgam. Claiming that alternatives are more expensive and of lesser quality is not a fair or accurate representation of these products. We believe that the legislator should take account of this evolution.

The WHO noted that “*recent data suggest that RBCs [resin-based composites], perform equally well as amalgam*”.<sup>37</sup> Whilst WHO findings do show dental amalgams outlast these alternatives, it highlighted a benefit linked to the use of the RBCs: “*Adhesive resin materials [such as composite] allow for less tooth destruction and, as a result, a longer survival of the tooth itself. Funding agencies should take the initiative and encourage the replacement of amalgam as the material of choice for posterior teeth with adhesive systems.*” The WHO report pointedly adds: “*it may be more important to examine tooth survival and to preserve tooth structure than filling survival*”.<sup>38</sup>

A 2012 European Commission BIO Intelligence Service (BIOIS) Study, commissioned by the European Commission, explains that given “*the results of recent studies comparing the longevity of different materials, in the present study it is considered that the longevity of Hg-free fillings is no longer a factor with significant effect on the overall cost difference between dental amalgam and composite or glass ionomer restorations*”.<sup>39</sup> BIOIS also notes on that same page that 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*”.

As for the health and environmental risks of the alternatives, a 2012 literature review (commissioned by Health Care Without Harm) conducted by researchers at the University of Illinois concluded that “*though data gaps continue to exist for the health effects of the alternatives to mercury amalgam, other than individual allergies to components of one or another composite, there is no current evidence of significant personal or environmental toxicity*”.<sup>40</sup>

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actively collaborating in amalgam phase down efforts. Use of mercury-free alternatives is a part of dental schools' obligatory training. In the Netherlands the dental schools stopped teaching the placement of amalgam between 1995 and 2005, on a voluntary basis.

<sup>35</sup> [http://www.strategyr.com/MarketResearch/Dental\\_Restorative\\_Supplies\\_Market\\_Trends.asp](http://www.strategyr.com/MarketResearch/Dental_Restorative_Supplies_Market_Trends.asp)

<sup>36</sup> Global Dental Restorative Supplies Industry (2016) :

[http://www.strategyr.com/MarketResearch/Dental\\_Restorative\\_Supplies\\_Market\\_Trends.asp](http://www.strategyr.com/MarketResearch/Dental_Restorative_Supplies_Market_Trends.asp)

<sup>37</sup> WHO Report (2010) *Future use of materials for dental restoration*, page 11

<sup>38</sup> Ibid, pages 16, 27

<sup>39</sup> European Commission (DG ENV), BIO Intelligence Service (BIOIS) (2012) *Study on the Potential for Reducing Mercury Pollution from Dental Amalgam and Batteries*, page 69

<sup>40</sup> Serap Erdal, Ph.D. and Peter Orris, M.D., M.P.H (2012) *Mercury in Dental Amalgam and Resin-Based Alternatives: A Comparative Health Risk Evaluation*, page 6

Leaving these reports and studies to one side, it is important to note that 4 EU member states have virtually phased out dental amalgam. In Hungary, amalgams are reportedly only used in 12% of all fillings. Beyond the EU, other countries such as Japan and Singapore have also moved away from dental amalgam and are using alternatives.<sup>41</sup>

## 6 – COST OF ALTERNATIVES

Those favouring a *status quo* approach to dental amalgam containing mercury often argue the cost of alternatives to dental amalgam is prohibitive, but this argument is at best spurious and at worst disingenuous. We therefore believe a fair assessment of the cost should include the following considerations<sup>42</sup>:

Firstly, externalities linked to the use of amalgams are rarely computed when calculating the cost of dental amalgam. The *Staff Working Document (SWD/2016/017)* of the European Commission states clearly that *“the fact that Hg-free dental restorations are more expensive than dental amalgam restorations can be seen as a market failure, in the sense that negative externalities associated with the use of dental amalgam (e.g. management of dental waste and effluents) are not factored in the market price of dental amalgam restorations. If these externalities were included, it has been shown – for the US market – that the market price of an average amalgam restoration would be equal to or up to about 15% higher than the price of a composite restoration”*.<sup>43</sup>

Secondly, empirical evidence from countries where a ban on dental amalgam exists, shows that *“the cost of mercury-free restoration has continued to decline with new technologies, and with further training and experience of dental practitioners”*.<sup>44</sup>

Thirdly, the 2016 UNEP report, *Lessons from countries phasing down dental amalgam use*, refers to the responses to a survey questionnaire which confirms that *“previous findings that traditional health insurance schemes often contain an inherent financial incentive in favour of amalgam”*.<sup>45</sup> The report goes on to explain that when Sweden decided to stop financial support for amalgam fillings from the national dental insurance service, the cost of amalgam increased for patients resulting in a drop of dental amalgam use.

Lastly, there is the real but hard-to-compute social effect and cost on society analysed by some scientists. Today, one out of every six children suffers from some form of neurodevelopmental abnormality. These scientists explain that the brain's development is uniquely sensitive to toxic chemicals, and even small deficits may negatively impact our academic achievements, economic success, risk of delinquency, and quality of life.

<sup>41</sup> UNEP (2016) *Lesson from countries phasing down dental amalgam use*, pages 11-13

<sup>42</sup> Concorde (2012) *The real cost of dental amalgam*: [http://mercurypolicy.org/wp-content/uploads/2012/04/real\\_cost\\_of\\_dental\\_mercury\\_april\\_2012-final.pdf](http://mercurypolicy.org/wp-content/uploads/2012/04/real_cost_of_dental_mercury_april_2012-final.pdf)

<sup>43</sup> SWD/2016/017 final - 2016/023 (COD) Commission Staff Working Document Ratification and Implementation by the EU of the Minamata Convention, page 146.

<sup>44</sup> UNEP (2016) *Lesson from countries phasing down dental amalgam use*, page 11

<sup>45</sup> Ibid, page 23

This is a huge human and financial cost to society. These scientists regard chemicals such as mercury as posing an insidious threat to the development of the next generation's brains.<sup>46</sup>

## 7 – WASTE TREATMENT COST

Failing a phase-out of dental amalgam, the EU member states will have to continue investing in a whole range of processes and hardware to at best mitigate the effects of mercury release during the whole life cycle of dental amalgam, i.e. mercury production, preparation of filling materials, and placement of new ones. Member states will need continue to manage the environmental and health impacts of mercury recycling, discharges into wastewater, solid waste disposal, emissions from crematoria, and releases from cemeteries.

In addition to the obvious costs of amalgam separators and amalgamators, the use of dental amalgam requires substantial investments in pollution control devices in crematoria. This is by far the most costly mercury emissions abatement measure. The 2016 UNEP report therefore concludes that it is much more cost-effective to eliminate the need for such pollution control devices over time by phasing down the use of amalgam fillings.<sup>47</sup>

Another challenge that member states will continue to face if a phase-out of dental amalgam is not carried out, is the increased cost of managing and disposing of sewage sludge contaminated by dental mercury released to wastewater.<sup>48</sup> Annex II of this paper graphically represents the battery of measures that will need to be maintained absent a phase-out.

## 8 – INSURANCE SCHEMES

Where appropriate, countries should examine how national insurance practices may be revised to help phase down amalgam use. Likewise, third party payment systems for dental care can also be adapted so as to help phase down amalgam use.

<sup>46</sup> Grandjean Philippe (2013) *Only One Chance, How Environmental Pollution Impairs Brain Development—and How to Protect the Brains of the Next Generation* (New York: Oxford University Press, 2013). See also How dentistry affects your life – Mercury and Parkinson's: <http://amalgam.org/education/scientific-evidenceresearch/mercury-parkinsons/>. They warn that there has been a huge increase in the incidence of degenerative neurological conditions in virtually all Western countries over the last two decades. The increase in Parkinson's and other motor neuron disease has been over 50%. The primary cause appears to be increased exposures to toxic pollutants, such as toxic metals, pesticides, etc., resulting in brain inflammation and oxidative damage of free radicals. Dental amalgam fillings are the largest source of mercury in most people with daily exposures documented to commonly be above government health guidelines. Also interesting is the book published by WHO in 2006: *Neurological Disorders: Public Health Challenges* ([http://www.who.int/mental\\_health/publications/neurological\\_disorders\\_ph\\_challenges/en/](http://www.who.int/mental_health/publications/neurological_disorders_ph_challenges/en/)), which discusses the magnitude of the public health challenge resulting from Alzheimer's and Parkinson's disease. They focus on the patients' age the economic burden that society has to shoulder as a result of these medical conditions. See also the increasing rates for Alzheimer documented by the WHO: <http://www.who.int/mediacentre/factsheets/fs362/en/>.

<sup>47</sup> UNEP (2016) *Lessons from countries phasing down dental amalgam use*, page 16

<sup>48</sup> Concorde (2012) *The real cost of dental amalgam*, page 16 and European Commission (DG ENV), BIO Intelligence Service (BIOIS) (2012) *Study on the Potential for Reducing Mercury Pollution from Dental Amalgam and Batteries*, page 88

The 2016 UNEP report, *Lessons from countries phasing down dental amalgam use*, refers to the responses to a survey questionnaire which confirms that “previous findings that traditional health insurance schemes often contain an inherent financial incentive in favour of amalgam”.<sup>49</sup> The report goes on to explain that when Sweden decided to stop financial support for amalgam fillings from the national dental insurance service, the cost of amalgam increased for patients, resulting in a drop of dental amalgam use.

## 9 – PRODUCERS OF DENTAL AMALGAM

The staggered phase-out of dental amalgam proposed by the Draft Eck Report should not have a damaging effect on market of amalgam producers. The 2016 report *Global Dental Restorative Supplies Industry* provides a detailed analysis of the restorative supplies market by geographic region and country.<sup>50</sup> However, the publicly available information is less recent. The *Staff Working Document* (SWD/2016/017) of the European Commission reports that: “out of 62 companies producing dental filling materials in the EU, 38 produce exclusively mercury-free materials and would not be affected at all by any measure restricting the use of dental amalgam to its encapsulated form. There are 20 companies producing both dental amalgam and mercury-free fillings, half of them located in Germany. Only 3 companies had been identified as producing solely mercury for dental restoration applications, two of them trading solely mercury for dental amalgam in bulk form either directly to dental practices or to the manufacturers of dental amalgam capsules. One company produces solely dental amalgam alloys (silver/copper/tin) and precious metals alloys for crown and bridge work”.<sup>51</sup>

## General points on the Proposal

Whilst the focus of this Position Paper is on the use of mercury in dental amalgam (Article 10 of the Proposal), we would like to express our general support for the European Parliament ENVI report prepared by Stefan Eck (GUE, DE). Below are some points we wish to highlight. Our views on these are aligned with the EEB Proposals to Ensure a Robust Revised EU Mercury Regulation.<sup>52</sup>

- **Legal basis:** The legal basis for the Proposal should only be Article 192 (1) of the Treaty on the Functioning of the European Union, and not Article 207. The legal basis should indeed reflect the main objective of the Proposal, which is the protection of human health and the environment. Trade issues are ancillary.
- **Export of mercury added products:** The export of mercury-added products not allowed to be marketed in the EU shall be prohibited (to avoid double standards and ensure they are not reaching countries with no or less stringent regulations to manage mercury) since alternatives exist, such a measure will promote mercury-free markets and drive prices down.

<sup>49</sup> UNEP (2016) *Lessons from countries phasing down dental amalgam use*, page 23

<sup>50</sup> Global Dental Restorative Supplies Industry (2016) :

[http://www.strategyr.com/MarketResearch/Dental\\_Restorative\\_Supplies\\_Market\\_Trends.asp](http://www.strategyr.com/MarketResearch/Dental_Restorative_Supplies_Market_Trends.asp)

<sup>51</sup> SWD/2016/017 final - 2016/023 (COD) Commission Staff Working Document Ratification and Implementation by the EU of the Minamata Convention, page 36

<sup>52</sup> [http://www.zeromercury.org/index.php?option=com\\_phocadownload&view=file&id=213:eeb-proposals-to-ensure-a-robust-revised-eu-mercury-regulation-sent-to-envi&Itemid=15](http://www.zeromercury.org/index.php?option=com_phocadownload&view=file&id=213:eeb-proposals-to-ensure-a-robust-revised-eu-mercury-regulation-sent-to-envi&Itemid=15)

- **Industrial use of mercury:** The use of mercury in industrial facilities located in the EU, where mercury is used as catalyst or electrode, should be prohibited: mercury free processes exist since the 1970s in many cases (e.g. chlor-alkali).
- **Mercury waste:** Waste mercury should be solidified/stabilised before disposal in underground facilities, providing additional safety during handling and disposal. Conditions for environmentally safe disposal of waste metallic mercury and mercury sulphide should be set, and be stricter than those for temporary storage.
- **Trade tracking system:** A comprehensive trade tracking system needs to be set up, to record information from exports and imports of elemental and compound mercury between member states, the EU, external countries, and also within the industry sector, to better know where the mercury is. (p.10, point 10)
- **Scope of the export ban:** The scope of the export ban should be expanded to include additional mercury compounds and mercury waste. The ban should cover all of the mercury compounds mentioned in the Minamata Convention and should also be included in Annex I, namely mercury(II) sulphate, mercury(II) nitrate, and mercury sulphide should be added.
- **Mercury use in artisanal and small-scale gold mining (ASGM):** We support the Eck Report's proposal to develop economic alternatives to ASGM.

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Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) (2015) *Opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users*

- [http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenihr\\_o\\_046.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf)

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WHO Report (2010) *Future use of materials for dental restoration*

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## Key documents and legislation

### **MINAMATA CONVENTION**

**Minamata Convention Text and Annexes** (October 2013)

▣ [http://www.mercuryconvention.org/Portals/11/documents/Booklets/Minamata Convention on Mercury\\_booklet\\_English.pdf](http://www.mercuryconvention.org/Portals/11/documents/Booklets/Minamata_Convention_on_Mercury_booklet_English.pdf)

### **EUROPEAN COMMISSION PROPOSAL ON MERCURY**

**COM (2016) 39 final** *Proposal for a Regulation of the European Parliament and of the Council on mercury, and repealing Regulation (EC) No 1102/2008*, 2 February 2016

▣ [http://eur-lex.europa.eu/resource.html?uri=cellar:f1bacfbb-c995-11e5-a4b5-01aa75ed71a1.0002.02/DOC\\_1&format=PDF](http://eur-lex.europa.eu/resource.html?uri=cellar:f1bacfbb-c995-11e5-a4b5-01aa75ed71a1.0002.02/DOC_1&format=PDF)

**SWD/2016/017 final - 2016/023 (COD)** *Commission Staff Working Document Ratification and Implementation by the EU of the Minamata Convention on Mercury Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on mercury, and repealing Regulation (EC) No 1102/2008*

▣ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016SC0017>

### **EUROPEAN PARLIAMENT REPORT**

**COM (2016)0039 – C8-0021/2016 – 2016/0023(COD) – Draft Report (Eck Report) on the proposal for a regulation of the European Parliament and of the Council on mercury, and repealing Regulation (EC)**

- <http://www.europarl.europa.eu/sides/getDoc.do?type=COMPARL&reference=PE-584.224&format=PDF&language=EN&secondRef=01>

### **RELEVANT MERCURY LEGISLATION**

**Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury (Text with EEA relevance)**

- <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R1102>

**Council Directive 2011/97/EU of 5 December 2011 amending Directive 1999/31/EC as regards specific criteria for the storage of metallic mercury considered as waste**

- <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0097>

### **PRODUCTS LEGISLATION**

**Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009**

**Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment**

- <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32002L0095>

**Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance)**

- <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410>

**Directive 2008/12/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators, as regards the implementing powers conferred on the Commission**

- <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:076:0039:0040:EN:PDF>

**Commission Regulation (EU) No 847/2012** of 19 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards mercury Text with EEA relevance – Restricts the use of mercury in several measuring devices (e.g. thermometers, sphygmomanometers, barometers) for industrial and professional uses from 10 April 2014.

■ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012R0847>

**Commission Regulation (EU) No 848/2012** of 19 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards phenylmercury compounds Text with EEA relevance – Prohibits the manufacture, use and placement on the market of five phenylmercury compounds from 10 October 2017.

■ <http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32012R0848>

#### **OTHER KEY LEGISLATION**

**Directive 2000/60/EC** of the European Parliament and the Council of 23 October 2000 establishing a framework for Community action in the field of water policy – Lists mercury as a priority substance in the field of water policy

■ [http://ec.europa.eu/health/endocrine\\_disruptors/docs/wfd\\_200060ec\\_directive\\_en.pdf](http://ec.europa.eu/health/endocrine_disruptors/docs/wfd_200060ec_directive_en.pdf)

**Directive 2013/39/EU** of the European Parliament and the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy (Text with EEA relevance)

■ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013L0039&from=EN>

**Directive 2004/107/EC** of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air – This is the Fourth Daughter Directive and completes the list of pollutants initially described in the Framework Directive<sup>53</sup>. Target values for all pollutants except mercury are defined for the listed substances, though for PAHs, the target is defined in terms of concentration of benzo(a)pyrene which is used as a marker substance for PAHs generally. Only monitoring requirements are specified for mercury.

■ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004L0107>

<sup>53</sup> Council Directive 96/62/EC on ambient air quality assessment and management is commonly referred to as the Air Quality Framework Directive. It describes the basic principles as to how air quality should be assessed and managed in the Member States. It lists the pollutants for which air quality standards and objectives will be developed and specified in legislation.

**Directive 2008/105/EC Environmental Quality Standards Directive** – Sets standards for mercury content in water. This Directive lays down environmental quality standards (EQS) for priority substances and certain other pollutants as provided for in Article 16 of the Water Framework Directive 2000/60/EC (WFD), with the aim of achieving good surface water chemical status and in accordance with the provisions and objectives of Article 4 of that Directive.

■ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:348:0084:0097:en:PDF>

**Industrial Emissions Directive (IED) (2010)** – Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control). The IED is the main EU instrument regulating pollutant emissions from industrial installations.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:334:0017:0119:en:PDF>

**Priority Substances and Certain Other Pollutants according to Annex II of Directive 2008/105/EC** – Priority Substances: 33 substances or groups of substances are on the list of priority substances for which environmental quality standards were set in 2008. Note that mercury and its compounds feature 21<sup>st</sup> on that list.

■ [http://ec.europa.eu/environment/water/water-framework/priority\\_substances.htm](http://ec.europa.eu/environment/water/water-framework/priority_substances.htm)

## Annexes

### ANNEX I – AMALGAM SEPARATORS IN THE EU – LEGAL REQUIREMENTS

The table details the legal requirements applicable to amalgam separators in the EU, Norway and Switzerland.

	COUNTRY	LEGAL REQUIREMENT?	COMMENT	SINCE
1	AUSTRIA	Yes	Actively enforced	1995
2	BELGIUM	Yes		2002
3	BULGARIA	No	Amalgam separators are only advised and they are not mandatory	
4	CROATIA	Yes	The EU Hazardous Waste Directive is incorporated into law and actively enforced. Amalgam separators are legally required.	
5	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
6	CZECH REPUBLIC	Yes	Amalgam separators have been obligatory since 2004, as part of a dental unit. 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.	2004
7	DENMARK	Yes	The Hazardous Materials Act is very strict – and amalgam is on the list. 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.	
8	ESTONIA	No	Amalgam separators are not required by law, although they are advised.	
9	FINLAND	Yes	The EU Hazardous Waste Directive 91/689 was incorporated into Finnish laws in 1993. Amalgam separators have been legally required since 1997.	1993
10	FRANCE	Yes	The EU Hazardous Waste Directive (requiring amalgam waste to be collected as hazardous waste) has been incorporated into French law. Amalgam separators have been legally required since 1998 in all units, requiring the collection of	1998

			95% of the weight of the amalgam in waste water.	
			There are regulations restricting who collects the waste to registered or licensed carriers.	
11	GERMANY	Yes	There are regulations to cover the disposal of clinical waste (Richtlinie für Abfallversorgung in Einrichtungen des Gesundheitswesens). There is a special Directive concerning amalgam separators (Richtlinie zur Indirekteinleiter-Versorgung), permission to load used water into public systems. Amalgam separators have been obligatory since 1990.	1990
12	GREECE	Yes	Amalgam separators are required by Common Ministerial Decision in 2003: "Handling and Management of Hazardous Waste Materials: Regulations cover the disposal of clinical waste.	2003
13	HUNGARY**	Yes	<p>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. According governmental guidance on environmental management of waste amalgam should be stored and carried as a biohazard.</p> <p>Amalgam separators are not required by law for existing units, but are where new units are equipped. The use of separators is recommended or advised by environmental managements for all units. By 2013, approximately 70%, of practices were equipped. Centrifugal or tank-type separators are used.</p> <p>The collection of dental amalgam is made by registered, licensed carriers. It is separated from other hazardous dental waste. The dentists or the owner of the practice, are liable for the procedure. The collected amalgam waste is recycled. The collected amalgam scrap (i.e. the mixed amalgam not used for the filling) is also collected and carried as bio-hazardous waste, but separately and is also recycled.</p>	
14	IRELAND	No	<p>Amalgam separators are not compulsory by law.</p> <p>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 book where these operations should be always written and described - about stored quantities.</p>	



15	ITALY	No	<p>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 book where these operations should be always written and described - about stored quantities.</p> <p>Amalgam separators are not compulsory by law.</p>
16	LATVIA	Yes	<p>Operations with hazardous waste are determined by the Law of Hazardous Waste. The necessity (need) 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.</p>
17	LITHUANIA	No	<p>The EU Hazardous Waste Directive has been incorporated into Lithuanian laws. It is actively enforced. Amalgam separators are not mandatory. Amalgam is not popular with patients or dentists.</p>
18	LUXEMBOURG	Yes	<p>The EU Hazardous Waste Directive has been incorporated into law and is actively enforced. Amalgam separators are legally required.</p>
19	MALTA	Yes	<p>The EU Hazardous Waste Directive is incorporated into law and actively enforced. Amalgam separators are legally required.</p>
20	NETHERLANDS	Yes	<p>Amalgam separators have been required in practices by law since 1997. Disposal of clinical waste may be only using certified companies. Regulations for Health and Safety Based on Guidelines for Infection Control inoculation against Hepatitis B is mandatory for dental workers.</p>
21	POLAND	Yes	<p>The EU Hazardous Waste Directive has been transposed into Polish law. However, amalgam separators are not mandatory in dental practices. Regulations restrict the collection of waste dental amalgam to registered carriers.</p>
22	PORTUGAL	No	<p>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.</p>
23	ROMANIA	No	<p>Amalgam separators are not required by law.</p> <p>There are special orders of the Ministry of Health relating to the disposal of clinical waste. There is</p>

			compulsory verifiable collection and incineration of biohazard contaminated medical and dental waste.	
24	SLOVAKIA	Yes	The EU Hazardous Waste Directive is incorporated into law and actively enforced. Amalgam separators are legally required.	
25	SLOVENIA	Yes	Amalgam separators are legally required in all practice units.  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.	
26	SPAIN**	Yes	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
27	SWEDEN	Yes	Amalgam separators have been required by a national law, since January 1999. The requirement applies to all units or premises. If waste is not disposed of according to national regulations the dentist is liable.	1999
28	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 waste dental amalgam 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.	
29	ICELAND	Yes	The EU law on the disposal of clinical waste are enforced. Since the year 2000 amalgam separators have been mandatory and there are regulations for the safe disposal of clinical waste.	2000



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responsible  
healthcare

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Without Harm

30	NORWAY	Yes	Amalgam separators are required by law – since 1996 1996. The waste amalgam must be collected by a registered carrier.
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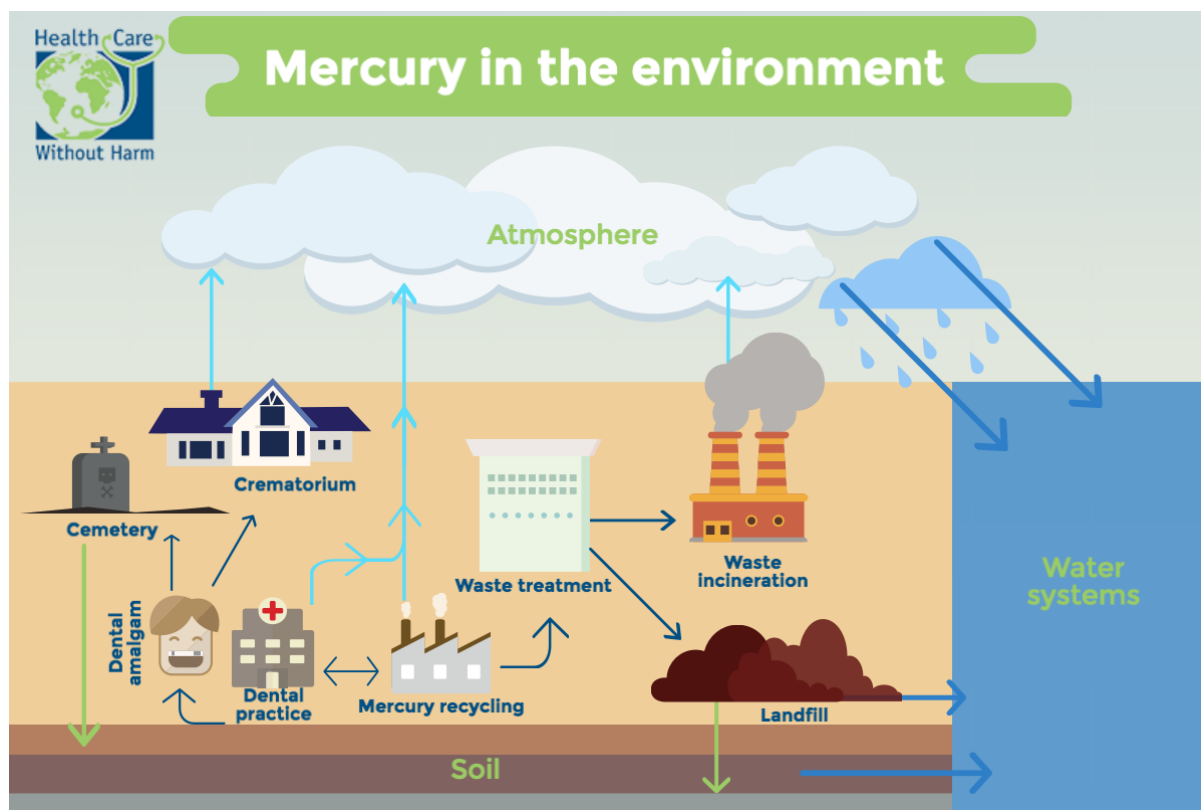
31	SWITZERLAND	Yes	Whilst the Swiss are not enacting the EU Directive, there are regulations to cover the disposal of clinical waste, including the installation of amalgam separators.
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Amalgam separators have been required by law  
for many years.

(\*\* New units only)

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

## ANNEX II – POSSIBLE MERCURY RELEASES TO THE ENVIRONMENT FROM DENTAL CARE



Source: HCWH Europe (2016)