

# *Study on the assessment of the feasibility of phasing out dental amalgam*

## *Technical Terms of Reference*

### **1. BACKGROUND**

#### **EU Mercury Strategy**

The Commission has adopted its Mercury Strategy<sup>1</sup> in 2005 setting out 20 actions with the aim to reduce mercury levels to the environment and human exposure. Two of the actions (4 and 6) of the Strategy concern dental amalgam.

In the 2005 communication, the Commission had already expressed its intention to undertake a review of the Mercury Strategy as a whole by the end of 2010. To this effect, the Commission requested BioIntelligence Service S.A.S to prepare a study, examining the progress of its implementation, assessing the success of the policies and corresponding measures, and proposing additional actions if needed. The final report of this study has been made available on DG ENV's mercury webpages since October 2010.<sup>2</sup> Phasing-out the use of dental amalgam was listed among the potential measures to be taken in order to reduce demand for mercury.

The Commission issued a new Communication<sup>3</sup> to the European Parliament and the Council on the review of the Community Strategy Concerning Mercury on 7.12.2010. In this Communication, the Commission expressed its intention to undertake in 2011 a study to assess the use of mercury in dental amalgam with due consideration to all aspects of its lifecycle.

#### **Minamata Convention on Mercury**

Due to the long-range transport properties of mercury, the exposure of people living in the Union as well as the exposure of the EU's environment cannot be reduced to an acceptable level through domestic policies alone. Co-ordinated international action is therefore needed to address the mercury problem in a globally effective manner.

The "[Minamata Convention on Mercury](#)" was adopted at a Diplomatic Conference in Japan in October 2013. By mid-June 2018, it counted 93 ratifications, including the EU and 21 EU Member States. Dental amalgam is among the products listed in Annex A of the Convention as a mercury-added product to be regulated under the Convention.

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<sup>1</sup> Communication from the Commission to the Council and the European Parliament, Community Strategy Concerning Mercury, [COM/2005/0020](#)

<sup>2</sup> [http://ec.europa.eu/environment/chemicals/mercury/pdf/review\\_mercury\\_strategy2010.pdf](http://ec.europa.eu/environment/chemicals/mercury/pdf/review_mercury_strategy2010.pdf)

<sup>3</sup> Communication from the Commission to the European Parliament and the Council on the review of the Community Strategy Concerning Mercury, [COM\(2010\)723final](#)

## **Regulation 2017/852 on Mercury**

Before the Minamata Convention was agreed, the EU already had in place a comprehensive body of mercury-related legislation, regulating trade in mercury, marketing restrictions for products containing mercury, waste aspects, water quality aspects, and emissions and releases from large point sources. Additionally, EU law sets maximum levels of mercury in food and prohibits the use of mercury in pesticides. Specific legislation was adopted in 2008<sup>4</sup> (Mercury Export Ban Regulation) that prohibits the exports of metallic mercury from the EU and regulates its safe storage.

In February 2016, the European Commission tabled a proposal for a Regulation on Mercury<sup>5</sup> in order to align the EU to the Minamata Convention and enable the EU to ratify it. The Commission's proposal was supported by an Impact Assessment<sup>6</sup> that covered all new provisions. It proposed two risk management measures concerning the use of dental amalgam, i.e. limiting the use of dental amalgam to pre-dosed capsules and making dental amalgam separators mandatory, but did not propose limiting the use of dental amalgam.

Dental amalgam has been a major issue addressed in the legislative process. This led to consensus that the use of dental amalgam is undesirable and should be phased-out if this is feasible.

Hence, the resulting Regulation 2017/852 on Mercury<sup>7</sup>, addresses the use of dental amalgam comprehensively, including in particular its phase down and phase-out.

In Recital 21, the legislator states that:

- *dental amalgam is the largest use of mercury in the Union and a significant source of pollution;*
- *dental amalgam should therefore be phased down in accordance with the Convention and with national plans;*
- *the Commission should assess and report on the feasibility of a phase out of the use of dental amalgam in the long term, and preferably by 2030, and*
- *particular preventive health protection measures should be taken for vulnerable members of the population, such as children and pregnant or breastfeeding women.*

Recital 22 and 23 further expand on specific risk prevention measures and training of practitioners.

Restrictions on the use of dental amalgam are set out in Article 10 of the Regulation on Mercury, including the following:

- Article 10(2): *From 1 July 2018, dental amalgam shall not be used for dental treatment of deciduous teeth, of children under 15 years and of pregnant or*

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<sup>4</sup> [Regulation \(EC\) 1102/2008](#), OJ L304 of 14/11/08, p.75.

<sup>5</sup> [COM/2016/039final](#)

<sup>6</sup> [SWD/2016/017final](#)

<sup>7</sup> [Regulation \(EU\) 2017/852](#), OJ L137 of 24/5/2017, p.1

*breastfeeding women, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient.*

- Article 10(3): *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*

Article 19(1)(b) tasks the Commission to report to the European Parliament and to the Council on the outcome of its assessment regarding:

- b) the feasibility of a phase-out of the use of dental amalgam in the long term, and preferably by 2030, taking into account the national plans referred to in Article 10(3) and whilst fully respecting Member States' competence for the organisation and delivery of health services and medical care; and*

Article 19(3) requires the Commission, if appropriate, to present a legislative proposal together with its report.

### **Dental amalgam**

In a study report "*Options for reducing mercury use in products and applications and the fate of mercury already circulating in society*"<sup>8</sup> carried out for the European Commission in 2008, dental amalgam was identified as the second biggest use of mercury in the EU. The study on the "*Review of the Community Strategy Concerning Mercury*" mentioned above identified Actions 4 and 6 of the Mercury Strategy, both linked to dental amalgam, as areas where substantial improvement could still be achieved.

In implementing the Community Strategy Concerning Mercury, the Commission services consulted two Scientific Committees on the environmental impact and human safety of dental amalgam, the Committee for Environmental and Health Risks (SCHER) and the Committee for Emerging and Newly Identified Health Risks (SCENIHR). They concluded that available studies on human population did not allow concluding that the Hg in dental amalgam had a causative role in disease.

The SCENIHR opinion has been updated in 2015<sup>9</sup> on the basis of more recent scientific evidence. It concluded that "*for the first treatment for primary teeth in children and in pregnant patients, alternative materials to amalgam should be the first choice*".

Concerning the environmental aspects, the SCHER was updated in 2014<sup>10</sup> and concluded that in a worst case scenario, a risk of secondary poisoning due to methylation of mercury cannot be excluded.

Commission Decision 2000/532/EC<sup>11</sup> characterises amalgam waste from dental care as hazardous waste, it is therefore subject to the provisions of the Waste Framework Directive<sup>12</sup>. Mercury emissions from dental cabinets are also subject to EU water legislation. Mercury is classified as priority hazardous substance according to Annex X of

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<sup>8</sup> [http://ec.europa.eu/environment/chemicals/mercury/pdf/study\\_report2008.pdf](http://ec.europa.eu/environment/chemicals/mercury/pdf/study_report2008.pdf)

<sup>9</sup> [https://ec.europa.eu/health/sites/health/files/scientific\\_committees/emerging/docs/scenihr\\_o\\_046.pdf](https://ec.europa.eu/health/sites/health/files/scientific_committees/emerging/docs/scenihr_o_046.pdf)

<sup>10</sup> [https://ec.europa.eu/health/scientific\\_committees/environmental\\_risks/docs/scher\\_o\\_165.pdf](https://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_165.pdf)

<sup>11</sup> OJ L226/3 of 6/9/2000

<sup>12</sup> Directive 2008/98/EC, OJ L312/3 of 22.11.2008

the Water Framework Directive (WFD)<sup>13</sup>, thus Member States are obliged in the long term to take measures to cease or phase-out the emissions, discharges and losses of this substance. In addition and reflecting the combined approach of the WFD, Directive 2008/105/EC<sup>14</sup> establishes Environmental Quality Standards in the field of water policy for certain priority substances including mercury and its compounds. In case these standards are not met, Member States have to take measures to comply with them as foreseen by Article 11 WFD.

The Commission had reviewed actual practices in dental clinics in Member States through a questionnaire survey carried out in 2005. It was concluded that while in many Member States the installation of amalgam separators was obligatory and appropriate collection schemes have been established, this is not the case throughout the Union. Reports from some Member States had indicated that even some of the mercury collected may end up in waste incinerators or landfills, rather than recycling. A significant quantity of human dental inventory of mercury (estimated at over 1000 tonnes for the entire EU population) will probably ultimately end up in the environment, e.g. to soil via burial, or even directly to the atmosphere following cremation.

Article 10(4) of the Regulation on Mercury establishes specific obligations for the use of amalgam separators from dental facilities. While the above considerations may not be central in examining the technical feasibility of phasing out dental amalgam, they should be taken into consideration when examining the economic aspects linked to its use.

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<sup>13</sup> Directive 2000/60/EC, OJ L327 of 22.12.2000

<sup>14</sup> OJ L348/89 of 24.12.2008

## **2. OBJECTIVES**

The objective of the study is to assist the Commission in assessing the feasibility of a phase-out of dental amalgam preferably by 2030, as required by Article 19(1)(b).

In particular, the study should examine the current situation in relation to the use of dental amalgam in the EU and assess the technical and economic feasibility of its phase-out. In this respect, it should look into the effects the phase-out of dental amalgam by 2030 would have on different market players and the environment. The study should take account of national specificities including any existing national phase-out measures, national phase-down plans due by July 2019 and specificities of national health services, including the extent to which they fund use and removal of dental amalgam, that may affect feasibility of a phase-out by 2030.

The study should gather all necessary information for undertaking an impact assessment should the incoming Commission decide to consider the presentation of a legislative proposal on phasing-out of dental amalgam. The study should therefore identify and assess the potential environmental, economic and social impacts of such a phase-out. It should allow all relevant Member State authorities, companies involved, non-governmental organisations active in this field and other stakeholders to provide relevant information.

The study should cover EU Member States but should also take into account the global perspective.

The relevant Commission guidelines<sup>15</sup> should be used as a basis for carrying out this task.

## **3. CONTENT / DESCRIPTION OF THE TASKS**

### **Task 1: Summary of relevant available information.**

T 1.1 Summarise available information on the environmental pressures (e.g. emissions to air, water and soil, amalgam waste management) of the use of dental amalgam in the EU.

T 1.2 Summarise available information on health aspects (e.g. exposure of the practitioner and of patients) relevant to the use of dental amalgam.

These tasks should be undertaken using available information, including the reports referred to in these terms of reference and other relevant publications. While the focus will be on scientific literature in the English language, the contractor should have the capacity to extend the review to literature in French, German or other languages, if necessary. The report to be provided to the Commission should include detailed results of the literature searches carried out, including complete bibliographic references, as well as copies/reprints of the most important publications identified. Links to the electronic versions of the documents should be provided where available.

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<sup>15</sup> [COM\(2017\)350 final](#), 4.07.2017

## **Task 2: Establish current and forecast future use levels**

T 2.1 Establish the level of dental amalgam use in each Member State for a reference year (e.g. 2016 or 2017 depending on availability of data) and the current increasing or decreasing trend of such use.

T 2.2 Establish a forecast of the use of dental amalgam in each Member State for the years 2020, 2025 and 2030 according to a business as usual scenario. This shall take into account the effects of Art 10(3) of Regulation 2017/852 and potential use reductions expected from the national phase down plans due by Member States by July 2019. It shall also take into account the impact of any other relevant EU law identified in the course of the study.

## **Task 3: Member State fiches on dental amalgam**

The contractor shall draft a fiche for each Member State gathering all Member State specific information relevant for this study. The fiches shall include the following:

- Dental amalgam use in reference year and current trend of such use (summary of the outcome of Task 2);
- Summary of national policy and regulatory measures applying to the use of dental amalgam, including a summary of the national phase down plan;
- Where the Member State has already prohibited dental amalgam use (e.g. Sweden), a case study on the phase-out and its implementation including any lessons learned and environmental and health benefits achieved that would be relevant for a phase-out at EU level;
- A description of the specificities of the national health services and funding of those services, which are relevant for assessing the feasibility of a phase-out.

## **Task 4: Market review**

A thorough market review on dental amalgam and mercury-free alternatives with focus on the European market should be conducted within this task. This should include, *inter alia*, estimates on market overview, quantities used, market shares, imports/exports, costs and prices, companies involved and distinguish costs for private operators and public operators.

The starting point for the work of Task 3 should be existing reviews such as studies prepared for the Commission accessible at <http://ec.europa.eu/environment/chemicals/mercury/>, for example:

- the comprehensive report on "*Options for reducing mercury use in products and applications and the fate of mercury already circulating in society*"<sup>16</sup> prepared by COWI A/S, under a study contract with the Commission.or
- The "*Study on the potential for reducing mercury pollution from dental amalgam and batteries*"<sup>17</sup> carried out by Bio Intelligence Service S.A. for the European Commission in 2012.

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<sup>16</sup>Contract:ENV.G.2/ETU/2007/0021,[http://ec.europa.eu/environment/chemicals/mercury/pdf/study\\_report2008.pdf](http://ec.europa.eu/environment/chemicals/mercury/pdf/study_report2008.pdf)

<sup>17</sup> [http://ec.europa.eu/environment/chemicals/mercury/pdf/final\\_report\\_110712.pdf](http://ec.europa.eu/environment/chemicals/mercury/pdf/final_report_110712.pdf)

Factors that may influence the market must be identified and analysed. For example, existing legislation in the various Member States, differences in health insurance schemes that may affect the use of dental amalgam, etc.

#### **Task 5: Assess the feasibility of phase-out of dental amalgam by 2030**

The contractor shall, based on the information gathered under other tasks, undertake an assessment of the feasibility of phasing-out the use of dental amalgam by 2030.

This shall include *inter alia*:

- An assessment of the technical feasibility of a phase-out, including with regard to the availability of substitutes, the safety/risk profile of substitutes, technical advantages and drawbacks and any limitations of using substitutes (e.g. special needs of patients), availability of equipment/techniques needed by dentists, availability of required dentists skills and training.
- An assessment of the economic feasibility of a phase-out, in particular:
  - The identification of winners and losers, the impact on costs of healthcare and how any cost change would be distributed, the impact on international trade in mercury and in the EU internal market. Insurance/reimbursement schemes and their influence on patient preferences should also be examined and compared;
  - A special focus on the potential impacts of a phase-out on national health services and insurances, including the identification of means and time needed for national health services to adapt to phase-out and an assessment of whether this will be challenging, taking into account the specificities and phase down plans of each Member State.

#### **Task 6: Summary of the potential impacts of a phase-out of dental amalgam by 2030**

T 6.1 The contractor shall establish an inventory of all environmental, economic and social impacts that could reasonably be expected from a phase-out of dental amalgam by 2030. Where information collected when undertaking the other tasks has not covered potential impacts, the contractor shall seek to gather relevant information or, if this proves unavailable, make justified assumptions regarding the impacts concerned.

T 6.2 The contractor shall summarise all information gathered in the course of this study on the environmental, economic and social impacts of a phase-out of dental amalgam by 2030 compared to business as usual. This shall *inter alia*:

- Take into account the full life cycle impacts of dental amalgam and its substitutes;
- Include a quantification and monetisation of environmental impacts;

The approach to assessing uncertainty in the analysis should be explained.

### **Task 7: Stakeholder workshop**

The contractor shall present the findings of the study in a one-day workshop, with participation of Member State and other stakeholders experts (around 100 participants).

The workshop will be held in Brussels and organised by the Commission services (DG ENV.C.4) on a date to be agreed with the contractor. In principle, this should take place towards the end of the study on the basis of the draft final report when preliminary conclusions of the feasibility assessment can be made available to participants.

The contractor shall prepare all documents for the workshop (agenda, presentations, draft report) and prepare a detailed report of the workshop discussions, including any written input received from Member States and other stakeholder participants after the workshop.

The Contractor shall take account of all relevant outcomes of the workshop when drafting the final report.