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**Conference of the Parties to the  
Minamata Convention on Mercury  
Fourth meeting**

Online, 1–5 November 2021\*

Item 4 (a) (ii) of the provisional agenda\*\*

**Matters for consideration or action by the Conference of  
the Parties: mercury-added products and manufacturing  
processes in which mercury or mercury compounds are  
used: information on dental amalgam**

**Information on the implementation of any additional measures  
taken by parties and on non-mercury alternatives to dental  
amalgam**

**Note by the secretariat**

As is mentioned in the note by the secretariat on the matter (document UNEP/MC/COP.4/5), the information received from Governments on the implementation of any additional measures taken by parties is set out in annex I to the present note, and information on non-mercury alternatives to dental amalgam is set out in annexes II and III. The submission is reproduced as received, without formal editing.

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\* The resumed fourth meeting of the Conference of the Parties to the Minamata Convention on Mercury is to convene in-person in Bali, Indonesia, and is tentatively scheduled for the first quarter of 2022.

\*\* UNEP/MC/COP.4/1.

## Annex I

### Information on the implementation of any other measures taken by parties

Implementation of the Minamata Convention on Mercury on the use of dental amalgam : Africa Phases Down Amalgam Use with Multiple Measures, moving toward Phase Out.

#### FOREWORD

*Africa is delighted to submit to the Secretariat a snapshot of the progress made on the continent on phasing down dental amalgam and its readiness to make dental amalgam history*

#### PROCESS

From the negotiations to the adoption of the Minamata Convention on Mercury in 2013, Africa, the second largest continent in size and in population, has led the way toward mercury-free dentistry. During the negotiations, Africa proposed a framework for how to reduce substantially amalgam use substantially, a framework that was largely adopted as Annex A-II. Immediately after its adoption, the Abuja Declaration for Mercury-Free Dentistry for Africa (2014) launched the campaign toward phaseouts; the next year, francophone Africa held a conference in Abidjan to focus on how to move toward mercury-free dentistry. In 2019, dentists from across the continent launched the network Dentists for a Mercury-Free Africa – brining dentists together with governments and NGOs to work unified for mercury-free dentistry.

At COP3 in 2019, a unified Africa Region proposed the phasing out of amalgam; the proposal led to a landmark Decision of the Parties which called on the Parties to accelerate the phasing down of amalgam use and called on the Secretariat to produce two reports, one on alternatives and one on successful measures to phase down amalgam use. We provide this comment for the latter – to advise the Secretariat of the significant and diverse steps being taken by African countries in the transition to mercury-free dentistry.

Africa is ready for modern, non-toxic, tooth-friendly dentistry. Amalgam is none of these – it is a polluting material, tooth-unfriendly, little changed from the 19<sup>th</sup> century. As Europe moves to phasing out amalgam in this decade, Africa fully intends to keep pace. What the region will not accept is continuing shipment in Africa of a mercury materials being abandoned in the West. The era of shipping toxic products to Africa that are banned elsewhere is over, now!

Africa has focused on these measures and these strategies to transition to mercury-free dentistry:

1-End of amalgam use for children: Before Europe ended amalgam for children, Mauritius did, in 2014.

2-End amalgam use for women of childbearing age: Reaching beyond protecting women who are pregnant or breastfeeding, and recognizing that a woman's body containing mercury is a risk to a future child she may bear, Tanzania in 2020 adopted, via the Tanzania Guidelines, an end to amalgam for all women of childbearing age, plus all children. The Guidelines are phased in, to take effect in 2023. See "Ministry of Health, Community Development, Gender, Elderly and Children, *The Second Guidelines for Provision of Oral Health Services in Tanzania* (2020)," <https://mercuryfreedentistry.files.wordpress.com/2020/06/tanzania-guidelines.pdf>

3-Stakeholder consensus to end amalgam: Zambia and Côte D'Ivoire have reached a consensus of all major stakeholders from civil society – dentistry, consumers, environmentalists – and the relevant government agencies that amalgam should be phased out. Guinea is moving toward that same consensus.

4-Dentist association support to end amalgam: The Nigerian Dental Association in 2020, agreeing with others from civil society, adopted a resolution to end amalgam for children in 2022, and to end amalgam for all in 2024; the dental association has written the government ministries to ask that the resolution be made into government policy.

5-Build consumer awareness via information sheets: Nigeria's federal government adopted an information sheet to guide parents and consumers to choosing mercury-free dentistry.

6-Africa Day for Mercury-Free Dentistry, October 13: Each year, NGOs across Africa launch public information campaigns marking this day and calling for action to phase out amalgam.

7-Media outreach by civil society: NGOs in Congo-Brazzaville and Ghana, and elsewhere, have done major media initiatives to alert consumers and parents about the risks of dental amalgam. The government of Djibouti has taken it upon itself to inform dental practitioners through several information and awareness sessions of the phase-down and ban measures that will be taken to move towards mercury-free dentistry. The Ministry in charge of the environment in Burkina Faso will undertake in 2021 a diagnostic study on the use of dental amalgam and the perception of the actors on the alternatives.

8-Model provinces programs: In Ben Arous, Tunisia; in Mombasa County, Kenya; in Edo State, Nigeria; and in Enugu State, Nigeria, conferences and programs focused on ending amalgam have occurred. At the top of the list in each of these model provinces is the end of amalgam for children.

9-Shift dental school curriculum to mercury-free dentistry: Cote d'Ivoire, Nigeria, and Senegal have updated dental school curriculum to promote mercury-free dentistry as the basis for oral health care.

10-End of amalgam use in hospitals and health systems: Benin, Madagascar and Cote d'Ivoire in its military hospitals, and Cameroun in its Baptist chain of hospitals and clinics, have ended amalgam use entirely.

11-National conferences focused on a transition to mercury-free dentistry: Guinea, Togo, Burundi, Senegal, Cameroun, Lesotho, Nigeria, Ghana, Congo-Brazzaville – and there are more – have held a national conference of stakeholders to build awareness and to initiate coordinated steps to end amalgam.

The pandemic slowed progress in 2020, of course. However, several countries are on the verge of announcing decisions.

Sincerely yours,

On behalf of the Africa region,

Roger BARO, Vice-President COP4,  
Ministry in charge of the Environment of Burkina Faso



L'Afrique s'est concentrée sur les mesures et les stratégies de transition vers la dentisterie sans mercure ci-dessous :

- 1- Fin de l'utilisation des amalgames chez les enfants : Avant que l'Europe ne mette fin à la pose de l'amalgame chez les enfants, l'Ile Maurice l'a fait, en 2014.
- 2- Fin de l'utilisation de l'amalgame chez les femmes en âge de procréer : Au-delà de la protection des femmes enceintes ou allaitantes, et de la reconnaissance du fait que le corps d'une femme contenant du mercure est un risque pour un futur enfant qu'elle peut avoir, la Tanzanie a adopté en 2020, par le biais des Lignes Directrices tanzaniennes, la fin de l'amalgame pour toutes les femmes en âge de procréer, ainsi que pour tous les enfants. Les Lignes directrices sont progressivement entrées en vigueur et la mesure d'interdiction totale entrera en vigueur en 2023. Voir « Ministry of Health, Community Development, Gender, Elderly and Children, *The Second Guidelines for Provision of Oral Health Services in Tanzania* (2020)»  
<https://mercuryfreedentistry.files.wordpress.com/2020/06/tanzania-guidelines.pdf>
- 3- Consensus entre les parties prenantes pour mettre fin à l'amalgame : la Zambie, la Côte d'Ivoire sont parvenues à un consensus entre toutes les principales parties prenantes – société civile, dentisterie, consommateurs, environnementalistes – et des organismes gouvernementaux concernés selon lequel les amalgames devraient être éliminés progressivement. La Guinée Conakry s'oriente vers ce même consensus.
- 4- Dentists for a Mercury-Free Africa : L'Association des Dentistes nigériens en 2020, s'accordant avec d'autres membres de la société civile, a adopté une résolution visant à mettre fin à l'amalgame chez les enfants en 2022 et à mettre fin à l'amalgame pour tous en 2024: l'association des Dentistes a écrit à différents départements ministériels pour demander que la résolution soit prise dans la politique du gouvernement.
- 5- Sensibiliser les consommateurs au moyen de fiches d'information : Le gouvernement fédéral nigérian a adopté une fiche d'information pour guider les parents et les consommateurs vers le choix de la dentisterie sans mercure.
- 6- Journée africaine de la dentisterie sans mercure, 13 octobre : Chaque année, des ONG à travers l'Afrique lancent des campagnes d'information du public à l'occasion de cette journée et appellent à des mesures pour bannir les amalgames.
- 7- Sensibilisation des médias par la société civile : Des ONG au Congo-Brazzaville et au Ghana, et ailleurs, ont pris d'importantes initiatives

médiatiques pour alerter les consommateurs et les parents sur les risques de l'amalgame dentaire. Le gouvernement de Djibouti a pris sur lui d'informer les praticiens de l'art dentaire au travers de plusieurs sessions d'information et de sensibilisation des mesures de réduction progressive et d'interdiction qui vont être prises pour aller vers une dentisterie sans mercure. Le ministère en charge de l'environnement du Burkina Faso va entreprendre en 2021 une étude diagnostique sur l'utilisation de l'amalgame dentaire et la perception des acteurs sur les alternatives.

- 8- Programmes des provinces modèles : À Ben Arous, en Tunisie; dans le comté de Mombasa, au Kenya; dans les États d'Edo et d'Enugu, au Nigéria, des conférences et des programmes axés sur la fin des amalgames ont eu lieu. Au sommet de la liste dans chacune de ces provinces modèles se trouve la fin de la pose de l'amalgame chez les enfants.
- 9- Changement des programmes d'enseignement des écoles dentaires vers une dentisterie sans mercure: La Côte d'Ivoire, le Nigeria et le Sénégal ont mis à jour le programme d'études dentaires pour promouvoir la dentisterie sans mercure comme base pour les soins buccodentaires.
- 10- Fin de l'utilisation des amalgames dans les hôpitaux et les systèmes de santé : Le Bénin, Madagascar et la Côte d'Ivoire dans leurs hôpitaux militaires, et le Cameroun dans tout le réseau des hôpitaux et cliniques Baptistes, ont complètement mis fin à l'utilisation des amalgames dentaires.
- 11- Des conférences nationales axées sur une transition vers la dentisterie sans mercure : La Guinée Conakry, le Togo, le Burundi, le Sénégal, le Cameroun, le Lesotho, le Nigeria, le Ghana, Congo-Brazzaville – et bien d'autres – ont organisé une conférence regroupant des parties prenantes nationales pour sensibiliser et initier des mesures coordonnées pour mettre fin à l'amalgame.

La pandémie a ralenti les progrès en 2020, bien sûr. Cependant, plusieurs pays sont sur le point d'annoncer des décisions.

Sincèrement vôtre,

Au nom de la région Afrique,

Roger BARO, vice-président COP4,  
Ministère en charge de l'Environnement du Burkina Faso



## BRAZILIAN MINISTRY OF HEALTH

Mercury-free alternatives to dental amalgam and additional measures  
implemented nationally for the decrease in the use of the product

### *ANNEX A: Mercury-added products/Part II: Products subject to Article 4, paragraph 3*

*Measures to be taken by a Party to phase down the use of dental amalgam shall take into account the Party's domestic circumstances and relevant international guidance and shall include two or more of the measures from the following list:*

- 1. Setting national objectives aiming at dental caries prevention and health promotion, thereby minimizing the need for dental restoration;*
- 2. Setting national objectives aiming at minimizing its use;*
- 3. Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental restoration;*
- 4. Promoting research and development of development of quality mercury-free materials for dental restoration;*
- 5. 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;*
- 6. Discouraging insurance policies and programmes that favour dental amalgam use over mercury-free dental restoration;*
- 7. Encouraging insurance policies and programmes that favour the use of quality alternatives to dental amalgam for dental restoration;*
- 8. Restricting the use of dental amalgam to its encapsulated form;*
- 9. Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.*



## MEASURES TO BE TAKEN BY BRAZIL FOR THE DECREASE IN THE USE OF DENTAL AMALGAM

### INTRODUCTION

Dental amalgam is an alloy composed mainly of silver (Ag), tin (Sn), and mercury (Hg), and other metals may be added to it. The percentage of mercury in the alloy ranges from 43% to 54%. Dental amalgam has physical and mechanical characteristics that make it one of the most resistant restoring materials in dentistry nowadays.

In oral health, all dental materials used have their pros and cons, and the choice of material to be used depends on the singularity of each patient, situation, and condition of the dental structure and on the availability of technology, infrastructure, and supplies.

The Brazilian Ministry of Health advocates that restoring techniques should be less invasive and less and less necessary and discourages the use of therapeutic techniques that promote a sharper deterioration of a healthy dental structure. It applies to the use of dental amalgam.

The Ministry of Health understands that the use of silver amalgam in certain specific situations is still necessary.

By virtue of the prevalence of dental caries in Brazil and of the economic impact that discontinuing the use of dental amalgam would create on the Unified Health System (SUS), it is considered that its gradual decrease should occur by (i) promoting actions of prevention and control, such as fluoridation of supply water, and investment in oral health in Primary Health Care and (ii) improving new materials (resin and ionomer) for the restoration of extensive carious lesions, so that their use is gradually decreased as the lesion is controlled and new technologies support the treatment.

It is known that the exposure to mercury creates a more direct impact on the health of the worker who manipulates it, however, the additional risk to the health of whoever has the amalgam should not be disregarded. Its incorrect disposal also provokes discussions about its impact on the environment. It is worth mentioning that there are several sources of human exposure to mercury and, in this regard, it is important to acknowledge that dental amalgam and mercury are not synonyms.<sup>1</sup>

Pursuant to the Minamata Convention on Mercury, Brazil has shown a decrease in the use of dental amalgam due to the changes inherent in the best performances of other dental materials and in the health-related increment of technological evolution, that is, as new dental materials improve, those used in the past are suppressed from day-to-day practice.

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<sup>1</sup> "Most of the mercury in the environment results from human activity, particularly from coal-fired power stations, residential heating systems and waste incinerators. Mercury is also present as a result of mining for mercury, gold (where mercury is used to form an amalgam before being burnt off), and other metals, such as copper, zinc and silver, as well as from refining operations." (WHO, 2007) - [https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUK Ewj7v9O23qLrAhXRRkGHf2TDvQQFjABegQIAxAB&url=https%3A%2F%2Fwww.who.int%2Fipcs%2Ffeatures%2Fmercury.pdf%3Fua%3D1&usq=AOvVaw0d\\_D1dGcfAaW3Bbu-TAj7p](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUK Ewj7v9O23qLrAhXRRkGHf2TDvQQFjABegQIAxAB&url=https%3A%2F%2Fwww.who.int%2Fipcs%2Ffeatures%2Fmercury.pdf%3Fua%3D1&usq=AOvVaw0d_D1dGcfAaW3Bbu-TAj7p)



## SUMMARY CHART

- Pursuant to the principles of the Unified Health System, Brazil has a universal, free oral health care model that includes actions of promotion, prevention, surveillance, treatment, and oral rehabilitation.
- The Brazilian Health System also promotes actions of continuing education, funds research institutions to carry out studies on minimally invasive techniques, minimal intervention dentistry, early treatment and handling of dental caries, in addition to providing oral health care in the scope of the Primary Health Care (APS).
- Nationally, there are rules and regulations for fluoridation of supply water and fluoride toothpastes. There are also recommendations regarding the use of other therapeutic techniques using fluorides, all within the scope of health promotion and prevention.
- The country conducts, every ten years, the “National Survey of Oral Health Situation” in order to guide the decisions related to the National Oral Health Policy (PNSB).
- Brazil has prohibited the non-encapsulated form of dental amalgam through national laws and regulations and has rules about the disposal of dental amalgam governed by the Brazilian Health Surveillance Agency – ANVISA.

Below, the Ministry of Health highlights the main actions related to measures “1, 2, 3, 4, 8, and 9” taken in order to decrease the use of dental amalgam, according to the provisions in part II of Annex A of the Convention and pursuant to its mandate in the health care sector.

1. **Setting national objectives aiming at dental caries prevention and health promotion, thereby minimizing the need for dental filling.**

The National Oral Health Policy (2004) forms part of the Unified Health System (SUS), which provides universal, free access to the entire population in Brazilian territory. The main objectives of the PNSB is the offer of oral health care to all people and access to oral health care by all people, based on the doctrinal principles of the SUS related to universalization, equity, integrity, decentralization, and popular participation.

Brazil emphasizes the actions of promotion and prevention for the decrease in the need for filling and/or the decrease in the prevalence of extensive cavitated lesions, as well as the need for restoring retreatment.

The Ministry of Health recommends the promotion of a healthy diet, aiming at the decrease in the excessive and frequent consumption of sugar (sucrose); the carrying out

of supervised dental brushing; the fluoridation of supply water,<sup>2</sup> monitoring and examinations of oral situation; as well as the use of materials that prevent the occurrence of more severe lesions, such as the use of fluoride varnishes, sealants, and fluoride gel.

Regarding the handling of dental caries, the SUS recommends to the population the right monitoring, promotion of self-care, healthy diet, and personal hygiene habits, so that the disease does not manifest clinically or that the intervention occurs in early stages, with a reduced need for filling and/or decrease in the prevalence of extensive cavitated lesions, as well as a decrease in the need for surgical-restoring treatment.

Brazil has 27,136 oral health care teams (eSB) that compose the family health care teams, with an estimated coverage of 43.63% in the scope of the APS (July/2020). In the basic health care facilities (UBS), the population subject to them<sup>3</sup> receives health care provided by eSB teams that perform functions of health promotion and oral diagnosis, treatment, and rehabilitation.

Schools and community centers are included in the field of action of the oral health care teams. The eSB teams have competences with the population under their sanitary responsibility such as health promotion, prevention and educational practices. It is recommended that they are approached timely for the identification of risk factors and the health-disease process. The Guidelines of the National Oral Health Policy establish that health promotion and prevention shall be priorities. Every ten years, a national survey of the oral health situation is conducted, within the scope of epidemiological surveillance.

Additionally, the Ministry of Health in 2020 recommended early intervention and oral health education since the gestational period, promoting Prenatal Dental Care (PNO). The health education that is recommended through the PNO aims at promoting a healthy gestation, with the adequacy of the oral environment and health education, recommending a healthy diet to pregnant women, with the lowest consumption possible of sucrose and sanitation of the teeth, reducing the chances of dental caries in the mother during this important stage.

The recommendation of the PNO, also in the field of health education, is that pregnant women breastfeed exclusively until the sixth (6<sup>th</sup>) month, and that, after the first teeth of the baby erupt, a fluoride toothpaste is used to brush them and manufactured or artificially-sweetened products are avoided, as recommended in the Food Guide for

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<sup>2</sup> With respect to fluorides, important allies to avoid the need for restoration, the Ministry of Health has strict rules related to concentration in a content suitable for human health, and it recommends its proper concentration described in Ordinance No. 2914 of December 12, 2012, on Water Potability for human consumption, which refers to Ordinance No. 635/GM/MS of January 30, 1976. Such ordinance provides for the Maximum Amount Allowed (VMP) in the Table of Annex VII, which is 1.5 ppmF. The other recommendations of use for fluorides are listed in a guide with an approach on the many different therapeutic techniques related to fluorides, in proper concentrations (*Guia de recomendações de uso de fluoratos* [Guide with recommendations of use for fluorides], 2009).

<sup>3</sup> To ensure the coordination of health care, expanding the access and competence of the teams acting in Primary Care, the National Primary Care Policy recommends: i. - That the population subject to each Primary Care team (eAB) and Family Health Care team (eSF) is of 2,000 to 3,500 people, located in its territory, ensuring the principles and guidelines of Primary Care. Link: <http://bvsms.saude.gov.br/bvs/saudelegis/gm/2017/MatrizesConsolidacao/comum/250693.html#:~:text=i,e%20diretrizes%20da%20Aten%C3%A7%C3%A3o%20B%C3%A1sica>.

Children under 2 (2019). The promotion of a healthy diet and oral health care habits since gestation and education of pregnant women in health will have an impact on the life of the children, who will have a better oral health situation, as it aims at reducing the prevalence of early dental caries during childhood, which affects the primary dentition.

Still in the scope of primary health care, the schools, recognized as practice spaces for health education and prevention of lesions, promoted the implementation of the *Programa Saúde na Escola* (PSE) [Health in School Program] (2007). The PSE was created in order to promote integration between education, actions of promotion, prevention, diagnosis, surveillance, and, especially, health education in public schools. In these actions, the students, the pedagogical staff, and the community are involved.

For the indigenous population, the Ministry of Health, through the Special Office for Indigenous Health (SESAI), organized free distribution of oral hygiene materials, composed of toothbrush, dental floss, and fluoride toothpaste. In addition to the development of several activities aimed at promoting the oral health of such populations for about 750,000 indigenous people who live in more than 5,000 villages.

The Ministry of Health recommends the following to the governmental entities:

- Expansion of the oral health coverage through the implantation of oral health care teams in the family health care teams, which must promote actions of promotion and prevention, identification of needs for treatment in early stages, health education, among others.
- Acknowledgement of territory, identification of risk groups and early-stage oral lesions for early intervention.
- Promotion of health education actions in collective environments, such as schools and community centers.
- Promotion of a healthy diet, aiming at reducing the excessive, frequent consumption of sugar (sucrose), risk factor for dental caries.
- Carrying out of supervised dental brushing.
- Fluoridation of supply water, as a collective means for controlling dental caries.
- Oral health surveillance, monitoring, examinations of oral situation, and the right registration of information in the primary care information system.
- Use of materials that prevent the occurrence or promote the staging of caries lesions, avoiding the progression of such injuries to a more severe stage, with the need for restoration.

## 2. Setting national objectives aiming at minimizing its use.



The Sectoral Plan for Implementation of the Minamata Convention, prepared by a Working Group of the health sector and established by Ministry of Health Ordinance No. 2,197, on July 20, 2018, aims at expanding and strengthening the country's institutional and technical capacities to identify, diagnose, treat, and monitor vulnerable populations; reducing and eliminating risks to human health arising from exposure to mercury and mercury-containing products; in addition to developing a research agenda and increasing the knowledge of the population and health professionals on the risks posed by the exposure to mercury, so that they also become an active part of the process to improve the proper management of this contaminant within the Brazilian territory.

Among the actions addressing dental amalgam contained in this Plan, attention is called to:

- Publication of Resolution No. 173, of September 15, 2017, of the Brazilian Health Surveillance Agency – ANVISA, which prohibited the manufacturing, importation, and sale, as well as the use in health services, of mercury and mercury powder for non-encapsulated amalgam alloy indicated for use in Dentistry become effective on January 1, 2019; It is important to highlight that specific explanatory materials were prepared and the oral health teams were informed about the prohibition of this type of dental amalgam by the Ministry of Health.
  - Creation of distinctions between restoring techniques in the information and monitoring system of the Ministry of Health. This action shall allow oral health teams to register the type of filling that shall be used as of 2020. This information shall be useful to verify the use of this dental material and other restoring techniques in the long term.
  - Preparation of a diagnosis of the dental amalgam use profile in the country's Basic Health Care Facilities with oral health professionals, which included the preparation and disclosure of an exploratory survey on consumer habits, use, and disposal of amalgam in Brazil.
  - Systematic review of the literature available on cost-effective and clinically effective mercury-free alternatives for dental filling, which includes the preparation of a Scientific Review on the safety of dental amalgam and a Scientific Review on the efficiency of dental amalgam and substitute materials.
  - Preparation of a Report on the use of amalgam within the scope of the indigenous health care subsystem.
3. Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental filling.

The Ministry of Health recommends researching about and enhancing the oral health approach focused on the promotion, prevention, minimal intervention, and maintenance of good health conditions by strengthening the incentives to self-management through tooth brushing and recommending the use of fluoride-containing products both by the population and oral health professionals. The main approach of the Federal Government

is to decrease the demand and need for dental filling of the population, encouraging and fostering oral health promotion and prevention.

Additionally, it is important to mention that the composite resin and glass ionomer are the main mercury-free restoring materials used to treat dental caries.

The Atraumatic Restorative Treatment (ART), recommended by the Ministry of Health (BRAZIL, 2007; 2018) uses only hand instruments and does not require electrical dental equipment and piped water. Among other advantages, it is possible to perform the ART fillings outside the healthcare facilities and in specific populations, such as those geographically isolated. Nevertheless, it is important to emphasize that the restoring material used in this technique (glass ionomer) does not have the same physical and chemical properties and clinical performance as the dental amalgam, and its lifespan is shorter than the amalgam's.

It is worth mentioning that, despite the technological evolution of glass ionomer cements, they show more wear and less resistance to fracture than resin and amalgam, which restricts their indication.

In remote regions of difficult access, where there is no timely dental assistance and reduced availability of dental equipment, as well as for persons in vulnerable situations, the dental amalgam may be the material of choice of oral health professionals, as it is more suitable for those situations.

It is known that the use of dental amalgam requires low technological capacity, while composite resin requires a dental curing light in good conditions of use to provide a good polymerization of the material (process of converting the resin into the plastic/solid state by light). Additionally, an adhesive system with good properties is necessary, allowing the resin to adhere to the dental substrate.

Nonetheless, the Indigenous Health Care Subsystem Report identified that, despite the increase in the total number of fillings carried out between 2015 ( $n = 150,440$ ) and 2018 ( $n = 270,946$ ), factor that may be associated with the increased access to dental services, that, in addition to developing assistance activities, also perform actions directed to prevention of dental caries and other oral health problems.

Despite the fact that the total number of fillings increased, the report identified that there was a decrease in the proportion of amalgam fillings in comparison with other materials. Amalgam fillings represented 10.3% ( $n = 15,565$ ) of the fillings performed in 2015, and this percentage dropped to 9.2% ( $n = 25,008$ ) in 2018. These numbers reflect a reduction trend in the use of the amalgam and an increase in the use of amalgam substitutes over time, with significant regional differences.

It is important to note that among indigenous groups, especially those from the northern region of the country, the consumption of certain ingredients and the way of preparing food may result in a hard and fibrous diet, such as moorhen flour, game meat, *moquéim* (meat roasted on embers, wrapped in banana leaf), seeds, coconuts, among others. Additionally, certain ethnic groups use teeth as a working tool to manufacture artifacts and household items, especially when the activity requires cutting and stripping fibers and vines.

Both the diet and the use of teeth in manufacture may be associated with the report that, in certain locations, there are indigenous peoples who show a preference for amalgam fillings over other materials, as they think the amalgam has better performance, more resistance, and longer lifespan.

Finally, we highlight that, according to the Scientific Review (DATS/HAOC/PROADI-SUS/2018), despite being mercury-free materials and despite being the patients' preferred alternative for mimicking the natural appearance of teeth, composite resins include in their formula a series of chemicals that may be released during the life cycle of the filling, from manufacturing to placement, removal, and disposal. These chemicals are mostly monomers and include compounds such as 2-hydroxyethyl methacrylate, triethylene glycol dimethacrylate, or monomers derived from Bisphenol A, according to Mulligan *et al.*, 2018.

The pollution potential of composite resins in the environment reflects the life cycle of the material, as well as the dental amalgam's. Despite the fact that BPA from monomers of the composite resin can be released in certain scenarios, the potential of this release is not well-defined.

#### **4. Promoting research and development of quality mercury-free materials for dental filling**

The Ministry of Health organizes Working Groups and promotes the integration with Health Research and Higher Education Institutions to improve and support continuing education for oral health care professionals in Brazil. In this regard, the most recent publication of the book "*A Saúde Bucal no SUS*" [Oral Health Care in the SUS] (2018) provided updates on the oral health care network, focusing on the APS, recommending minimally invasive techniques for treating dental caries, for example, based on the most recent scientific evidence.

The country conducts, every ten years, the "National Survey of Oral Health Situation" in order to guide the decisions related to the National Oral Health Policy (PNSB).

Two studies have been carried out by a research group of Cochrane Brazil (2020), whose research subjects and main findings were the following:

##### **1 – Study I: Hall Technique**

A technique that indicates the biological sealing of caries in primary molars in which preformed metal crowns (PMCs) are put using the Hall technique. The Hall technique used to insert preformed metal crowns (PMCs) in primary molars is a minimally invasive treatment option, because the caries are not removed, but rather they are sealed by cementing the crowns.

Researchers have concluded that such technique has advantages in comparison with conventional restoration techniques and conventional PMCs, because "it does not require the use of anesthetic, it does not require tooth preparation, or occlusal adjustments, and it



may be implemented in environments away from specialized dental centers and with non-specialized professionals. Additionally, the execution of the technique is simple, it takes less time, and it aims at reducing the child's stress and at facilitating the conduct of the professional".

## 2 – Study II: ART

A technique that indicates the removal of carious tissue using hand instruments and subsequent restoration using glass ionomer, using finger pressure, not requiring light curing polymerization.

Researchers have concluded that the clinical decision must be considered taking into account the possibility of using the ART technique as a clinical option. Given the advantages of the implementation of the ART technique, namely, the fact that it may be used in environments without electrical energy and that it requires simple instrumentation and less local anesthetic, this technology must be studied further. It is argued that the ART technique may have a better performance if it is implemented by trained professionals, who are attentive to the particularities of using the materials. The choice of materials with improved resistance must be considered.

## 8. Restricting the use of dental amalgam to its encapsulated form.

Brazil has adopted rules restricting the use of silver amalgam to its encapsulated form. The restriction of the use of amalgam only to its encapsulated form was defined by Collegiate Board of Directors' Resolution (RDC) No. 173 of September 18, 2017, of the Brazilian Health Surveillance Agency – ANVISA, which prohibits in the entire national territory the manufacturing, importation, and commercialization, as well as the use in health care services, of non-encapsulated mercury and powder for amalgam alloy indicated for use in Dentistry.

## 9. Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.

The right way to store traces of amalgam fillings and the right way to dispose of teeth with such fillings are described in ANVISA RDC No. 222/2018, which establishes that the collection of mercury waste resulting from the preparation of dental amalgam may occur in a sturdy, unbreakable container with a large mouth and made of an inert material.

There must be a water line over the waste stored in the container, which shall be sent to be restored or to another form of disposal in compliance with the rules defined by the competent environmental authority. The amalgam fillings being replaced by other materials are a bigger challenge. During their removal, the use of diamond dental burs and drills produces small amalgam granules that are removed from the mouth by suction devices that, on their turn, are disposed of directly into the sewerage system. A potential solution for proper disposal in such cases is the use of separating filters, which are studied and regulated by ANVISA.

## CHALLENGES IN THE IMPLEMENTATION OF ADDITIONAL MEASURES TO REDUCE THE USE OF DENTAL AMALGAM WITHIN THE POST- COVID-19 PANDEMIC CONTEXT.

The Research on the Oral Health Situation of the Brazilian Population (SB BRASIL), which was expected to be carried out in 2020, was postponed due to the current public emergency scenario caused by the Covid-19 pandemic. This study was supposed to assess the current landscape of the distribution of dental caries nationally, based on the DMFT (Decayed, Missing, and Filled Teeth) index.

Due to the Covid-19 pandemic scenario and to the fact that Sars-CoV-2 is transmitted by oral fluids, Brazil has promoted the suspension of elective dental treatments, which worries oral health care managers and professionals regarding the higher demand for dental treatments that is arising at this moment and that will arise in a post-pandemic scenario. In this regard, with the suspension of the elective treatments, suspension of health promotion and prevention practices, early identification of risk groups, and timely intervention for action in early stages of the disease, most likely, the need for restoration and the aggravation of the activity and severity of carious lesions will be noted. This scenario has been under examination in the Federal level, but it should also be considered in the assessment of the removal of therapeutic techniques from the SUS.

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REPUBLIQUE DU CAMEROUN  
*Paix – Travail – Patrie*

MINISTRE DE L'ENVIRONNEMENT,  
DE LA PROTECTION DE LA NATURE  
ET DU DEVELOPPEMENT DURABLE

SECRETARIAT GENERAL

DIRECTION DES NORMES  
ET DU CONTROLE

CONVENTION DE MINAMATA  
SUR LE MERCURE



REPUBLIC OF CAMEROON  
*Peace – Work – Fatherland*

MINISTRY OF ENVIRONMENT,  
PROTECTION OF NATURE AND  
SUSTAINABLE DEVELOPMENT

SECRETARIAT GENERAL

DEPARTMENT OF STANDARDS  
AND CONTROL

MINAMATA CONVENTION  
ON MERCURY

No. /L/MINEPDED/SG/DNC/FP

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**LE MINISTRE**  
**THE MINISTER**

A/TO

**Monika Stankiewicz**

Executive Secretary  
Secretariat of the Minamata Convention on Mercury  
International Environment House 1  
11-13 chemin des Anémones, 1219 Châtelaine, Geneva,  
Switzerland  
E-mail : MEA-MinamataSecretariat@un.org

**Subject:** Submission of informations related on follow-up the decisions adopted by the Conference of the Parties to the Minamata Convention at its third meeting (COP 3), Geneva, Switzerland, 25 to 29 November 2019

Referring to the Minamata Convention COP 3 decision concerning specifically the proposal of amendement of Annex A of the Convention,

Cameroon have the honour to express its solidarity and support for the regional submission of the African Group on this issue before presenting its specific comments below with regard of its national situation.

At the level of the country;

- about 25% of dentists use alternatives to dental amalgams (widely available on the national market), while 75% use both alternatives and dental amalgams;
- 83% of the dental amalgams used are in encapsulated form;
- the ease with which dentist place dental amalgam and its low cost are the main reasons why most dentist prefer these routes. However, certain dentist, who, because of their professional ethics, voluntarily decide to put an end to this practice;
- None of the dental clinic use or has a dental amalgam separator. This is to reduce mercury pollution resulting from services rendered.

The two main obstacles to overcome in order to ensure a complete transition and a technological leap from local dentistry to mercury-free dentistry within to the implementation of Minamata Convention are:

1. The lack of dexterity and competence of the dentists (individually) to conveniently use mercury-free alternatives on patients, and;
2. The low cost of dental amalgams, which is not in reality if all externalities are taken into account (harmful effects of mercury pollution from mercury in amalgams).

These two obstacles can be overcome through capacity building and cooperation (as mandated by the Minamata Convention on Mercury) one hand, and the adoption of specific regulations on dental amalgams by the Ministry of Public Health, on the other hand.

The following measures were proposed and supported by all national stakeholders during the implementation of the MIA project, these include;

- By January 1, 2020: partial ban on the use of dental amalgams in children, pregnant women and vulnerable patients;
- By January 1, 2025: total ban on dental amalgam for all;
- By January 1, 2025: capacity building for dentists through the Cameroon National Dental Council to use alternative materials and skills sharing activities;
- From now on: awareness raising in the faculty of dental medicine in both state and private medical institutions in the country, on the future of amalgam and the need to update training programs.

These proposals from national stakeholders have been transposed into a draft specific national regulatory on dental amalgams submitted to decision-makers.



The image shows an official circular stamp of the Ministry of Public Health of the Republic of Cameroon. The stamp contains the text "REPUBLIQUE DU CAMEROUN", "Ministère de la Santé Publique", and "Le Ministre". Overlaid on the stamp is a handwritten signature in black ink. Below the signature, the name "HELE Pierre" is printed in a bold, pink font.

**Canada's additional actions taken to phase down dental amalgam and implement a third provision listed in Part II of Annex A of the Minamata Convention on Mercury**

Canada has already implemented two of the measures listed in Part II of Annex A: measure (i) *setting national objectives aiming at dental caries prevention and health promotion, thereby minimizing the need for dental restoration*, and measure (ix) *promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land*. Canada has implemented measure (i) through the implementation of the *Canadian Oral Health Framework 2013-2018* and the *Canadian Oral Health Strategy 2005-2010*. In addition, the Canadian Ministry of Health (Health Canada) implemented the community-based *Children's Oral Health Initiative for First Nations and Inuit*, which focussed on the prevention of dental disease and the promotion of good oral health practices among children, their parents/caregivers, and pregnant women. Together, the strategy, framework and initiative work to minimize the need for dental restorations by setting out our national objectives.

Canada implements measure (ix) through the *Notice Requiring the Preparation and Implementation of Pollution Prevention Plans in Respect of Mercury Releases from Dental Amalgam Waste*. This notice requires dental facilities to prepare and implement a pollution prevention plan if they have not already implemented best management practices for dental amalgam waste.

Following decision MC-3/2, Canada undertook a [review of the available safety information](#) for dental amalgam and concluded that there is no clear link between mercury in dental amalgam and negative health effects. Although pre-measured dental amalgam capsules are considered safe, bulk dental amalgam powders, which have to be mixed with liquid mercury by hand, are known to pose an unnecessary risk of mercury exposure for the dental healthcare professional.

In Canada, dental amalgam is considered to be a medical device under the *Medical Device Regulations* of the *Food and Drugs Act* and its sale for use is controlled through the issuance of medical device licences by Health Canada. At the time of the 2020 review, six dental amalgam products containing bulk metal powder were authorized for sale. However, these products were no longer being used in Canada. Following its safety review, Health Canada worked with manufacturers to discontinue the licenses of bulk dental amalgam powders. This action has allowed Canada to additionally implement a third measure listed in Part II of Annex A: measure (viii) *restricting the use of dental amalgam to its encapsulated form*.



**MINISTRE DU TOURISME ET DE  
L'ENVIRONNEMENT**

**DIRECTION GENERALE DE  
L'ENVIRONNEMENT**

**POINT FOCAL CONVENTION DE  
MINAMATA SUR LE MERCURE**

**REPUBLIQUE DU CONGO  
Unité-Travail-Progress**

Brazzaville, le 25 janvier 2021

**Le Point Focal de la Convention de  
Minamata sur le mercure**

**A**

**M. Takafumi Anan,  
Secrétariat de la Convention de  
Minamata sur le Mercure  
takafumi.anan@un.org  
mea-minamatasecretariat@un.org**

**Objet : Soumission au Secrétariat sur l'amalgame dentaire**

Monsieur,

La République du Congo a signé la Convention de Minamata sur le mercure le 08 Octobre 2014 et l'a ratifié le 6 août 2019. Dans ce contexte et grâce au FEM, le Congo a eu les ressources pour réaliser le MIA (Evaluation initiale du Mercure) et le PAN (Plan d'Action National pour l'Extraction Minière Artisanale et à Petite Echelle de l'or de la République du Congo).

Concernant le MIA, L'inventaire de rejet du mercure réalisé au Congo pour la période temporelle 2013-2017 concernant les données recueillies, montre que la quantité globale de rejets de mercure est de 21 368 kg/an dont 373,31 kg/an (soit environ 2%) sont imputables à l'amalgame dentaire.

Pour mettre fin à l'amalgame dentaire en République du Congo, l'alternative proposée dans le MIA consiste à élaborer des mesures juridiques et administratives décourageant son utilisation dans le pays.

La société civile a été très active sur la question de l'amalgame dentaire.

L'association Action sur l'Environnement et le Développement (AED), partenaire du gouvernement, notamment du ministère en charge de l'environnement par Attestation de Reconnaissance du Ministère du Tourisme et de l'Environnement n°19/MTE/DGE/DDE du 07 janvier 2016 et dont le Président a été le Consultant Principal de l'Evaluation Initiale du Mercure au Congo, a mené organisé des ateliers de sensibilisation suivants:

- 15 mars 2017: La dentisterie sans mercure, pour les ONG, avec l'appui du Centre Africain pour la Santé Environnementale (CASE);



- 13 octobre 2017: Le danger du mercure dans l'extraction minière artisanale et à petite échelle de l'or, pour les parties prenantes, en coordination avec le projet PAN Congo;
- le plus important a été l'atelier de sensibilisation du 15 juin 2018 à Brazzaville, sur les risques causés par le mercure en vue de parvenir à la fin de l'utilisation de l'amalgame dentaire chez les enfants de moins de 15 ans, les femmes enceintes et les mères allaitantes, avec l'appui de l'Alliance mondiale pour une dentisterie sans mercure (WAMFD). L'atelier qui a eu un large succès a connu la participation des parlementaires, OSC, représentants des ministères de l'environnement et de la santé, et dentistes. Plusieurs recommandations y ont été faites, entre autres, l'élaboration d'une réglementation pour l'arrêt de la pose d'amalgame dentaire chez les personnes à risque.

Aussi l'AED a eu l'initiative de présenter en 2019 au Gouvernement, précisément au Ministère du Tourisme et de l'Environnement, un arrêté portant interdiction de la production, l'importation, la commercialisation et l'utilisation de l'amalgame dentaire pour obturer les cavités de la dent, notamment dans les traitements dentaires des mineurs de moins de quinze (15) ans et des femmes enceintes ou allaitantes. Un décret, plus général, réglementant la gestion du mercure et composés de mercure en République du Congo a été aussi présenté à cette occasion. Ces deux textes n'ont pas encore abouti.

Il faut noter qu'au Congo, certains dentistes ont déjà adopté les nouveaux matériaux alternatifs à l'amalgame dentaire. Il faut cependant reconnaître que nombre de praticiens continuent à le déposer dans les cavités des dents.

Au vu de ce qui précède, La République du Congo soutient une transition vers une dentisterie sans mercure. L'utilisation des amalgames doit être progressivement diminuée, parce qu'il s'agit :

- (1) le mercure est un polluant majeur ;
- (2) les coûts de gestion des déchets de mercure sont très élevés ;
- (3) le mercure dentaire empoisonne les aliments que nous consommons, en particulier les enfants ;
- (4) il est un risque pour la santé des enfants (moins de 15ans), des femmes enceintes et des femmes qui allaitent,
- (5) la pose de l'amalgame est un risque d'exposition à la vapeur de mercure à la fois pour les patients et les dentistes ainsi que les travailleurs des cabinets dentaires et ;
- (6) les alternatives à l'amalgame dentaire sont disponibles, modernes et supérieures.

La République du Congo, à travers les deux textes juridiques présentés ci-dessus, va mettre en place des mesures pour réduire progressivement l'utilisation des amalgames dentaires et initier la transition vers la dentisterie sans mercure.

Veuillez agréer, Monsieur, l'expression de ma franche considération.



**Geneviève BAZOMA DONGUI**



## **SOUMISSION DE LA CÔTE D'IVOIRE RELATIVE A LA DECISION DE LA CdP3 SUR LES AMALGAMES DENTAIRES**

### **CONTEXTE**

Le mercure est un métal lourd hautement toxique qui représente une menace pour la santé humaine et l'environnement au niveau mondial. Dans le monde entier, la présence de mercure a été détectée dans l'air, l'eau, le sol, la chaîne alimentaire ainsi que dans certains déchets et produits. Bien que présent naturellement dans l'environnement, le mercure est aujourd'hui principalement émis par les activités humaines telles que les procédés industriels, l'exploitation minière, l'incinération des déchets et la combustion de combustibles fossiles.

Avec ses divers composés, il présente une série d'effets graves sur la santé et est particulièrement nocif pour le système nerveux, le système immunitaire, les reins, les poumons, les yeux, les gencives et la peau. Il peut entraîner des pertes de mémoire et les dommages qu'il cause au cerveau sont irréversibles. Il n'existe pas de niveau d'exposition au mercure élémentaire qui soit sans risque pour le corps humain, des effets pouvant être constatés même à de très faibles concentrations. Les foetus, les nouveau-nés et les enfants sont parmi les plus vulnérables et les plus sensibles aux effets nocifs du mercure.

Les amalgames dentaires, matériau d'obturation contenant au moins 50% de mercure, font partie des produits contenant du mercure objet de préoccupation majeure pour la Côte d'Ivoire. En effet, au regard de l'évolution de la contribution des cabinets dentaires à la charge environnementale en mercure, plusieurs actions ont été menées pour réduire, et ce de façon significative, les amalgames dentaires dans la pratique dentaire.

La présente soumission se veut être un résumé de l'état d'avancement de la marche de la Côte d'Ivoire vers une dentisterie sans mercure. Pour rappel, la Côte d'Ivoire a



signé la Convention de Minamata, lors de la Conférence Diplomatique qui s'est tenue, du 7 au 11 octobre 2013 à Kumamoto – Japon et l'a ratifié le 1<sup>er</sup> octobre 2019.

#### 1- Les émissions de mercure en provenance des cliniques dentaires fortement élevées

En 2011, une première campagne de mesure dans quelques cabinets dentaire du pays a révélé des émissions élevées de mercure. Cependant, il eut fallu attendre 2016 pour qu'une campagne de mesure couvre une large plage de cabinets dentaires sur le plateau d'Abidjan, le centre-ville de notre ville la plus grande. En effet, les mesures effectuées ont montré des teneurs en mercure entre 250 et 4.636 ng/m<sup>3</sup>.

Cette campagne de mesure a permis de mettre en lumière les émissions issues des différentes phases du procédé de pose et dépose d'amalgame dentaire. En effet, il est ressorti que les émissions de mercure atteignent leurs pics dans l'air des cabinets dentaires au moment du retrait de l'amalgame de l'amalgamateur lors de la pose et aussi au cours du fraisage lors de la dépose d'amalgame<sup>1</sup>.

Les mesures faites dans les cabinets dentaires au niveau des bacs à ordures (situés à une hauteur de 0.5 m du sol) ont révélé des émissions de mercure dans l'air des cabinets oscillant entre 301 et 4.650 ng/m<sup>3</sup>. Cela dénote une contribution importante des déchets des cliniques dentaires à la charge mercurielle environnementale<sup>2</sup>. En effet, la quasi-totalité des cabinets dentaires ne possède pas de séparateur d'amalgame. Pour les cliniques qui en possèdent, ils sont tous non-fonctionnels. Ainsi, le mercure en provenance des cabinets dentaires se retrouve dans les déchets ménagers au niveau des décharges hospitalières ou des décharges municipales, ce qui pose la brûlante question de la gestion des déchets mercuriels au niveau national. De ce constat fait au niveau des séparateurs, le gouvernement a choisi l'option de ne pas fournir des séparateurs dans les cabinets au regard des coûts liés à la maintenance et surtout à la construction d'installations de traitement de déchets mercuriels en provenance des amalgames dentaires. En effet, nous trouvons moins coûteux – nous le répétons moins couteux – de terminer la transition vers les matériaux non polluants. Nous estimons encore que la solution à la pollution par les matériaux d'obturation toxiques est leur interdiction à la source, la fabrication et l'utilisation des matériaux non polluants.

Pour parer à ce problème, un ensemble de mesures promouvant les alternatives sans mercure est d'une nécessité pour la Côte d'Ivoire.

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<sup>1</sup> Mercury Vapor measurement during amalgam removal in dental clinic, 2017.

<sup>2</sup> Mercurial intoxication in dental clinic: Myth or reality in Côte d'Ivoire, 2017.

## 2- Les alternatives sans mercure nouvelle tendance d'usage

Dans le cadre de la mise en œuvre de la convention de Minamata par le gouvernement, plusieurs activités de sensibilisation ont été organisées. Il s'agissait notamment de :

- *L'atelier de sensibilisation sur les mesures de réduction progressives du mercure en dentisterie, organisé par le PNUE en collaboration avec le Centre Africain pour la Santé Environnementale et l'ONG Jeune Volontaire pour l'Environnement en avril 2015.*

Au sortir de cet atelier, le département d'Odontologie Conservatrice de l'UFR d'Odonto-Stomatologie de l'Université Félix Houphouët Boigny d'Abidjan a rappelé que les programmes d'enseignements sont modifiés depuis 2014 aux fins de mettre l'accent sur les alternatives sans mercure. L'accent a été renforcé et les étudiants de ce département utilisent essentiellement des alternatives sans mercure pour les soins cliniques. C'est ainsi que voit le jour la nouvelle génération de dentistes formés essentiellement à la pose de matériaux alternatifs pour les soins liés à la maladie carieuse. A ce jour, c'est à plus de 70% que les matériaux alternatifs sont utilisés en première intention de soins restaurateurs dans les cliniques dentaires rattachés à l'UFR d'odonto-stomatologie<sup>3</sup>. Ce qui déteint positivement sur l'ensemble des cabinets dentaires du pays, vu que les dentistes en formation pratiquent comme assistants dans la plupart des cabinets du pays.

Par la même occasion, les obstacles liés aux coûts élevés ont été levés en vue de vulgariser les alternatives par un faible coût du traitement. En effet, au niveau des hôpitaux publics, les coûts des soins d'obturation à l'amalgame oscillent entre 5.000 et 7.000 FCFA (10-15 USD) alors que les coûts des traitements restaurateurs aux CVI sont autour de 9.000 CFA (17 USD), lorsque ceux au composite varient entre 9.000 CFA 12.000 CFA (17 – 23 USD).

Cependant, au regard de la forte demande en matériaux alternatifs aussi bien par la population que par les praticiens eux-mêmes, les importations de CVI et de composites se sont accrues.

Dans le but de la promotion des alternatives sans mercure, depuis 2014, est célébrée par les OSC chaque 13 Octobre, la journée pour une « Afrique Sans Amalgame Dentaire ». Cette journée est le lieu pour les Organisations de la Société Civile oeuvrant pour l'élimination du mercure dans les produits de santé de faire la sensibilisation sur les dangers liés au mercure contenu dans les amalgames dentaires. Dans notre pays, cette journée de sensibilisation est pilotée par le Centre Africain pour

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<sup>3</sup> Echecs des restaurations postérieures aux résines composites : causes et manifestations cliniques en pratiques quotidiennes. Enquête auprès des chirurgiens-dentistes d'Abidjan, Revue du COSA CMF, Volume 27 N°1- Mars 2020.



la Santé Environnementale (CASE)<sup>4</sup>, laquelle organisation pilote aussi cette campagne pour toutes les organisations de la société civile africaine. Au cours de ces journées de sensibilisation, une lucarne est faite à la promotion de la dentisterie invasive à minima comme pratique dentaire pour le 21<sup>ème</sup> siècle mais aussi à une promotion de la santé bucco-dentaire comme outil de prévention de la maladie carieuse.

### 3- Des Mesures en attentes

Sous l'impulsion du Ministère de la Santé et avec la contribution du Centre Africain pour la Santé Environnementale (CASE), en juin 2018, un avant-projet de décret a été validé et suis son parcours administratif pour son adoption finale. Il porte sur l'interdiction des produits contenant du mercure ajouté listés à l'annexe A1 de la Convention et l'interdiction de l'usage de l'amalgame dentaire au mercure chez les enfants de moins de 15 ans et les femmes. Cela en vue de la conformité avec certaines mesures listées à l'annexe A2 de la Convention.

#### Le point Focal de la Convention de Minamata

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<sup>4</sup> <https://news.abidjan.net/h/624282.html>

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

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

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

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

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

From 1 July 2018, dental amalgam shall not be used for dental treatment of deciduous teeth, of children under 15 years and of pregnant or breastfeeding women, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient.

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

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

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

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

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

From 1 January 2019, operators of dental facilities in which dental amalgam is used for dental amalgam fillings or teeth containing such fillings are removed, shall ensure that their facilities are equipped with amalgam separators for the retention and collection of amalgam particles, including those contained in used water.

Such operators shall ensure that:

- (a) Amalgam separators put into service from 1 January 2018 provide a retention level of at least 95% of amalgam particles;
- (b) From 1 January 2021, all amalgam separators in use provide the retention level specified in point (a)

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

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

This report concludes that:

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



Ministero della salute

Ministero dell'ambiente e della tutela del territorio e del mare

Ministero dello sviluppo economico

*Piano nazionale per l'eliminazione dell'utilizzo dell'amalgama dentale*



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## **PREMESSA**

La Convenzione di Minamata sul mercurio prevede l'adozione di misure per eliminare progressivamente l'amalgama dentale e, a livello europeo, il Regolamento (UE) 2017/852 sul mercurio ha previsto, all'articolo 10, a far data dal 1° gennaio 2019, che l'utilizzo di amalgama dentale o la rimozione di otturazioni/elementi dentali contenenti tale materiale, siano effettuate esclusivamente su riuniti odontoiatrici dotati di separatori di amalgama (conformi ai requisiti tecnici indicati dal medesimo Regolamento 2017/852).

Lo stesso Regolamento, prevede, sempre all'articolo 10, comma 3, che ogni Stato membro definisca un Piano nazionale concernente le misure che intende adottare al fine di eliminare gradualmente l'utilizzo dell'amalgama dentale e che ciascuno Stato membro metta a disposizione del pubblico, su *internet*, il Piano di cui sopra e che questo venga comunicato alla Commissione entro un mese dall'adozione.

## **PIANO**

Il presente Piano descrive le azioni necessarie a conseguire la progressiva dismissione dell'uso (commercializzazione e impiego clinico) dell'amalgama dentale in ambito odontostomatologico, con il fine ultimo di pervenire ad una completa eliminazione (*phase-out*) di tale uso, tramite misure non coercitive, entro il 31 dicembre 2024.

La realizzazione di tale obiettivo si baserà, principalmente, su una diffusa azione di informazione e formazione riguardo a:

- adozione a livello internazionale e nazionale della strategia di eliminazione dell'utilizzo dell'amalgama;
- razionale di questa scelta;
- disponibilità sul mercato di materiali alternativi.

L'azione informativa e formativa sarà rivolta principalmente agli operatori del settore, tanto a quelli direttamente coinvolti nella filiera odontoiatrica (produttori; distributori; Associazioni professionali, Università e Società scientifiche di area odontoiatrica; CAO) che a quanti hanno frequenti rapporti professionali con gli odontoiatri (Medici di medicina generale, Pediatri di libera scelta). Sarà opportuno, tuttavia, prevedere anche iniziative di sensibilizzazione rivolte ai cittadini, anche attraverso il coinvolgimento delle associazioni dei consumatori.

Il Piano non prevede specifiche proposte o previsioni sulla rimozione di restauri in amalgama clinicamente soddisfacenti (salvo in presenza di accertate reazioni allergiche ad uno dei componenti dell'amalgama dentale stessa), in quanto tale operazione non presenta un favorevole rapporto tra rischi e benefici, né in termini di tutela della salute né di protezione ambientale.

Per il raggiungimento degli obiettivi del Piano, si rendono necessarie due pre-condizioni:

1. il coinvolgimento e la piena e costante collaborazione di tutti gli attori coinvolti nella tematica dell'amalgama dentale;
2. la possibilità di disporre routinariamente di informazioni affidabili relativamente alle vendite delle preparazioni di amalgama (e, possibilmente, al loro utilizzo clinico) e allo smaltimento degli scarti, anche al fine di verificare l'eventuale necessità di adottare un'apposita norma che disponga il divieto di commercializzazione e utilizzo clinico dell'amalgama dentale.

Le Istituzioni devono mirare ad ottenere la collaborazione di quanti, in Italia sono coinvolti nella gestione dell'amalgama dentale - attori istituzionali, professionali ed economici; in particolare occorrerà ottenere l'impegno volontario, ma formalizzato, di tali soggetti nel perseguimento degli obiettivi del Piano. Da questo punto di vista si rendono necessarie le seguenti azioni:

- prosecuzione della collaborazione interministeriale avviata in fase di predisposizione del Piano ai fini del follow-up dello stesso e valutazione del conseguimento dei relativi obiettivi nonché per garantire l'apporto sinergico delle specifiche competenze e conoscenze volte ad agevolare l'informazione e la formazione degli stakeholder interessati;
- identificazione, a partire da quanto avviato nelle fasi di stesura del Piano, dei principali soggetti da coinvolgere nella implementazione del Piano nell'ambito professionale (es: Collegio dei docenti di discipline odontostomatologiche, la Commissione Albo Odontoiatri Nazionale- CAO nazionale-, le Associazioni professionali (Associazione Nazionale Dentisti Italiani - ANDI; Associazione Odontoiatri Italiani -AIO; Associazione Dentisti Italiani – ADI) e in quello produttivo-commerciale (es: Unione Nazionale Industrie Dentarie Italiane - UNIDI, Associazione Nazionale Commercio Articoli Dentali – ANCAD);
- stesura e sottoscrizione di un apposito Protocollo d'intesa che traduca in precisi impegni le espressioni preliminari di disponibilità raccolte in fase di preparazione da parte degli stakeholders;

Per il monitoraggio dell'efficacia del Piano, occorre prevedere:

- dal 1° settembre 2020 (tempo zero), l'acquisizione, regolare e formalizzata, da parte del Ministero della salute, dei dati relativi alla vendita delle confezioni di amalgama in forma incapsulata e pre-dosata nelle varie modalità di confezionamento. Tale rilevazione sarà ripetuta periodicamente (almeno annualmente) con l'obiettivo di verificare l'effettiva riduzione delle vendite ai livelli ritenuti compatibili con il raggiungimento dell'obiettivo finale di una totale eliminazione del prodotto dall'uso;
- dal 1° gennaio 2021, ed a seguire, con cadenza annuale, l'acquisizione, da parte del Ministero dell'ambiente e della tutela del territorio e del mare, dei dati relativi ai volumi di scarti di amalgama ritirati e stoccati (codice CER 18 01 10);
- effettuazione di riunioni annuali con gli stakeholder facenti parte del Protocollo d'Intesa al fine di condividere i dati del monitoraggio e verificare l'assenza di criticità nel raggiungimento degli obiettivi prefissati dal protocollo stesso.

I competenti Uffici del Ministero della salute e del Ministero dell'ambiente e della tutela del territorio e del mare dovranno predisporre, entro il 30 giugno 2024, un documento che, sulla base degli ultimi dati disponibili alle Amministrazioni in quel momento, formuli indicazioni su eventuali ulteriori misure da adottare al fine di garantire la dismissione dell'uso dell'amalgama in ambito odontostomatologico.



## IMPLEMENTAZIONE DEL PIANO

Le successive Tabelle sinottiche descrivono in maniera sintetica le principali azioni connesse alla implementazione del Piano, con i relativi attori, tempistiche e risultati attesi, ai fini di facilitare il monitoraggio dello stato di implementazione e la valutazione della probabilità di successo del Piano. Le Tabelle elencano anche una serie di possibilità criticità, intese non come elementi ostativi attuali da risolvere preliminarmente, ma come elementi specifici da attenzionare precocemente nel monitoraggio in quanto particolarmente rilevanti nel processo di implementazione delle azioni.

**Tab 1. Collaborazione Attori**

<i>azioni</i>	<i>attori</i>	<i>tempi</i>	<i>risultato atteso</i>	<i>possibili criticità</i>
Prosecuzione operativa e revisione mandato/obiettivi del "Gruppo Tecnico deputato alla stesura del Piano nazionale concernente le misure che si intende adottare al fine di eliminare gradualmente l'utilizzo dell'amalgama" di cui al D.D. del 21 gennaio 2019	Ministero della salute  Ministero dell'ambiente e della tutela del territorio e del mare  Ministero dello sviluppo economico	Novembre 2020	Follow-up della implementazione e del conseguimento degli obiettivi del Piano	Mancata disponibilità Attori istituzionali
Identificazione dei soggetti professionali ed economici coinvolti nella filiera dell'amalgama	Gruppo tecnico interministeriale	Novembre 2020	Stesura di un elenco di Attori	
Verifica della disponibilità degli stakeholders e formalizzazione degli impegni	Ministero della salute  Ministero dell'ambiente e della tutela del territorio e del mare  Ministero dello sviluppo economico  Unione Nazionale Industrie Dentarie Italiane (UNIDI)  Associazione Nazionale Commercio Articoli Dentali (ANCAD)  CAO nazionale  Collegio dei Docenti di discipline odontostomatologiche  Associazioni professionali (ANDI, AIO, ADI)  Associazioni dei consumatori	Gennaio 2021	Stesura e sottoscrizione di un Protocollo di intesa	Assenza di obblighi partecipativi  Mancata disponibilità Attori professionali e economici  Mancata sottoscrizione del Protocollo

**Tab. 2 Monitoraggio**

<i>azioni</i>	<i>attori</i>	<i>tempi</i>	<i>risultato atteso</i>	<i>criticità</i>
Acquisizione ed estrazione dei dati di vendita dei fornitori appartenenti alla rete ANCAD, elaborazione dei dati di vendita su base geografica, trasmissione dei dati di vendita al Ministero della salute	ANCAD	Periodicamente (altmeno ogni anno) dal 2020 al 2024	Realizzazione di un monitoraggio dei dati di vendita di amalgama  Verifica della riduzione delle vendite	Mancata disponibilità dei dati in relazione alla volontarietà della comunicazione dei dati
Elaborazione dei dati ricevuti	Ministero della salute			
Disseminazione dei risultati su richiesta				
Estrazione dai modelli MUD dei dati relativi all'amalgama, trasmissione dei dati, elaborazione e caricamento dei dati relativi all'amalgama ritirata da parte di ISPRA, trasmissione dei dati da ISPRA a Ministero dell'ambiente e della tutela del territorio e del mare	Istituto Superiore per la Protezione e la Ricerca Ambientale (ISPRA)	Annuale dal 2021 al 2024	Realizzazione monitoraggio volumi di scarti di amalgama ritirati e stoccati a far data dal 01 - 01 - 2020	Difficoltà di estrazione dei dati relativi all'amalgama dal modello MUD
Analisi dei dati relativi ai volumi degli scarti di amalgama ritirati e stoccati	Istituto Superiore per la Protezione e la Ricerca Ambientale (ISPRA)			
Disseminazione dei risultati su richiesta	Ministero dell'ambiente e della tutela del territorio e del mare			

**Tab.3** Informazione e formazione

<i>azioni</i>	<i>attori</i>	<i>tempi</i>	<i>risultato atteso</i>	<i>criticità</i>
Definizione e predisposizione di un modulo formativo sulla tematica "amalgama dentale"	Università  Associazioni professionali degli esercenti la professione di odontoiatra	Dicembre 2020	Aumento del numero di odontoiatri formati sulle metodiche amalgama-free e sulle corrette procedure per la rimozione delle pregresse ricostruzioni in amalgama	Disponibilità alla attivazione di specifici percorsi formativi  Mancata partecipazione alle iniziative di formazione
Inserimento del modulo formativo nel piano di studi universitario o post laurea, ivi compresa la formazione ECM          Implementazione dell'attività formativa	Università  Enti di formazione e provider ECM    Università  Federazione Nazionale degli Ordini dei medici e degli odontoiatri (FNOMCeO)  Società scientifiche di area odontoiatrica  Medici di medicina generale  Pediatra di libera scelta	Entro il I semestre 2021		
Organizzazione di una giornata informativa (infoday) sulla tematica "amalgama dentale"	Ministero della salute  Ministero dell'ambiente e della tutela del territorio e del mare  Unione Nazionale Industrie Dentarie Italiane (UNIDI)  Associazione Nazionale Commercio Articoli Dentali (ANCAD)	Entro il I semestre 2021	Incremento odontoiatri informati sui materiali alternativi all'amalgama  Incremento cittadini informati sulla possibilità di ricevere cure conservative amalgama-free  Incremento cittadini informati sulle criticità legate all'uso dell'amalgama e sull'obiettivo di eliminazione dell'amalgama al 2024	Mancata partecipazione alla giornata formativa

Realizzazione di attività di informazione sulle problematiche legate all'utilizzo dell'amalgama dentale e sui materiali mercurio <i>free</i> utilizzati in odontoiatria conservativa, mediante pubblicazione sul sito web dei Ministeri competenti	Ministero della salute  Ministero dell'ambiente e della tutela del territorio e del mare	II semestre 2021	Incremento cittadini informati sulle problematiche legate all'utilizzo dell'amalgama dentale in termini di salute ed impatto ambientale	
Distribuzione, negli studi odontoiatrici, di materiale informativo sui materiali restaurativi amalgama <i>free</i>	Associazione Nazionale Commercio Articoli Dentali (ANCAD)  Associazioni professionali degli esercenti la professione di odontoiatra          Associazioni dei consumatori	I semestre 2021	Incremento odontoiatri a conoscenza dei materiali alternativi all'amalgama dentale          Incremento odontoiatri con consapevolezza a sull'assenza di giustificazioni alla rimozione non motivata di restauri in amalgama Incremento cittadini informati sulle problematiche legate all'utilizzo dell'amalgama dentale e sulla possibilità di richiedere ai dentisti l'utilizzo di materiali amalgama- <i>free</i> .	



**Tab. 4** Verifica

<i>azioni</i>	<i>attori</i>	<i>tempi</i>	<i>risultato atteso</i>	<i>possibili criticità</i>
Convocazione riunione con gli stakeholder al fine di condividere le azioni svolte, analizzare i dati del monitoraggio e verificare l'assenza di criticità	Ministero della salute Ministero dell'ambiente e della tutela del territorio e del mare Ministero dello sviluppo economico Unione Nazionale Industrie Dentarie Italiane (UNIDI) Associazione Nazionale Commercio Articoli Dentali (ANCAD) CAO nazionale Collegio dei Docenti di discipline odontostomatologiche Associazioni professionali (ANDI, AIO, ADI) Associazioni dei consumatori	Marzo 2022	Follow-up della implementazione e del conseguimento degli obiettivi del Piano	Mancata disponibilità Attori coinvolti

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2. *"Vivere bene entro i limiti del nostro pianeta".* Decisione n.1386/2013/UE del Parlamento Europeo e del Consiglio del 20 novembre 2013 su un programma generale dell'Unione in materia di ambiente fino al 2020
3. *"Divieto di utilizzazione, importazione e immissione in commercio, sul territorio italiano degli amalgami dentali non preparati sotto forma di capsule predosate e precauzioni ed avvertenze da riferire nelle istruzioni per l'uso degli amalgami dentali posti in commercio in Italia".* Decreto del Ministro della salute 10 ottobre 2001 (G.U. Serie Generale n.261 del 09-11-2001).
4. *"Study on the potential for reducing mercury pollution from dental amalgam and batteries. Final report".* European Commission -DG ENV -11 July 2012.
5. WHO (2010) *Future use of materials for dental restoration*  
a. ([www.who.int/oral\\_health/publications/dental\\_material\\_2011.pdf](http://www.who.int/oral_health/publications/dental_material_2011.pdf)).
6. *"Attuazione della direttiva 93/42/CEE concernente i dispositivi medici".* Decreto legislativo 24 febbraio 1997, n.46 (G.U. Serie Generale n.54 del 06-03-1997 - Suppl. Ordinario n. 49).
7. *"Indicazioni sull'utilizzo dell'amalgama dentale in ambito odontostomatologico",* Ministero della salute, Gruppo Tecnico sull'Odontoiatria, Sottogruppo "Amalgama" (Coordinatore: prof. Enrico Gherlone), 2018

## **GLOSSARIO**

Materiali mercurio <i>free</i>	materiali privi di mercurio utilizzabili in odontoiatria conservativa: trattasi di resine composite, cementi vetroionomerici, ceramiche, oro fuso
Modello Unico di Dichiarazione Ambientale (MUD)	è una comunicazione annuale al catasto dei rifiuti; consente di raccogliere ed elaborare statisticamente i dati sui rifiuti raccolti dai Comuni, prodotti da imprese ed enti, trasportati, intermediati, commercializzati e sottoposti a trattamenti finalizzati al recupero o allo smaltimento (DPCM del 24 dicembre 2018 - Gazzetta Ufficiale n.45 del 22 febbraio 2019)

### Submission from Japan on dental amalgam

In the decision MC-3/2, the Conference of the Parties to the Minamata Convention (COP), among other things, encouraged Parties to take more than two required measures in accordance with part II of Annex A to the Convention to phase down the use of dental amalgam, and requested the secretariat to collect information on the implementation of any such additional measures taken by Parties.

In addition, the COP requested the secretariat to collect from Parties and others information pursuant to paragraph 7, Article 4 of the Convention, i.e. information including that related to the availability, technical and economic feasibility and environmental and health risks and benefits of the non-mercury alternatives to the product.

Japan hereby submits the implementation of measures in accordance with part II of Annex A to the Convention to phase down the use of dental amalgam and relevant information.

Provision under the Convention		Measures and relevant information in Japan
(i)	Setting national objectives aiming at dental caries prevention and health promotion, thereby minimizing the need for dental restoration	"Health Japan 21 (2 <sup>nd</sup> edition)" published by the Ministry of Health, Labour and Welfare lays out goals related to the health teeth and oral health, including the prevention of tooth loss, increase of infants and school age children who do not have dental caries and increase of the proportion of those who have had a dental checkup over the year.
(ii)	Setting national objectives aiming at minimizing its use	—
(iii)	Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental restoration	In Japan, dental treatment with dental amalgam has been no longer covered by health insurance since the revision of the medical payment system in April 2016. Mercury-free alternatives for dental restoration have been listed as those covered by health insurance.
(iv)	Promoting research and development of quality mercury-free materials for dental restoration	Non-mercury alternatives such as gallium alloy have been developed and already available in Japan.
(v)	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	<ul style="list-style-type: none"> <li>■ "Model Core Curriculum for Dental Education (FY2016 Revision)" published by the Ministry of Education, Culture, Sports, Science and Technology lays out the objective for dental students to learn the cavity restoration with composite resin, glass ionomer cement and metal inlay, but nothing is noted about dental amalgam.</li> <li>■ The research on metal free materials, such as non-</li> </ul>



Provision under the Convention		Measures and relevant information in Japan
		metal prosthesis and fillings, has been ongoing, and relevant academic congress has also been held.
(vi)	Discouraging insurance policies and programmes that favour dental amalgam use over mercury-free dental restoration	Dental treatment with dental amalgam has been no longer covered by health insurance since April 2016.
(vii)	Encouraging insurance policies and programmes that favour the use of quality alternatives to dental amalgam for dental restoration	Same as above.
(viii)	Restricting the use of dental amalgam to its encapsulated form;	Dental amalgam has been rarely used since April 2016.
(ix)	Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.	— Note: Dental facilities must contract out the transportation and treatment/disposal of waste dental amalgam and issue a manifest to industrial waste management companies who possess appropriate licenses unless dental facilities themselves possess them in order to ensure the environmentally sound management of waste dental amalgam.
—	(Additional information)	Dental amalgam is currently not manufactured in Japan.

To the Minamata Secretariat, [mea-minamatasecretariat@un.org](mailto:mea-minamatasecretariat@un.org),  
cc to Mr. Takafumi Anan, [takafumi.anan@un.org](mailto:takafumi.anan@un.org), Dr. Mohammed Khashashneh,  
[mohamed.khashashneh@moenv.gov.jo](mailto:mohamed.khashashneh@moenv.gov.jo), [mkhashashneh@yahoo.com](mailto:mkhashashneh@yahoo.com).

**Subject: Jordan's Measures for the transition to Mercury-Free Dentistry  
(Information on Non-Mercury Alternatives to Dental Amalgam in Jordan)**

Dear Minamata Convention Secretariat:

I hope you are doing well, healthy and safe,

After consultation with H.E. Dr. Mohammed Khashashneh/ Acting Secretary-General of the Ministry of Environment/ Jordan, regarding the Jordanian efforts to achieve the transition from dental amalgam to non-mercury alternatives, where these efforts can be contributed with the Asian and Pacific countries' measures, and following the COP3 decision related to the Dental Amalgam, I would like to highlight some important issues in this regard in Jordan:

Jordan seeks to achieve the transition from dental amalgam to non-mercury alternatives because these non-mercury alternatives are available, feasible, and beneficial to health and the environment. Non-mercury alternatives are available, as proven by the many dentists (and entire countries) that rely on them exclusively.

A 2019 survey found that Jordanian dentists are already using more non-mercury composite than dental amalgam.<sup>[1]</sup> Also, in Jordan, there is a national health insurance program that covers dental care at a modest cost, so it will be economically feasible for all patients to receive non-mercury alternatives.

Non-mercury alternatives are beneficial to health and environment, where the transition from dental amalgam to non-mercury alternatives is particularly important in Jordan because, as our Minamata Initial Assessment found dental amalgam is one of the sources categories that made the largest contributions to mercury inputs in Jordan.[\[2\]](#)

And because Jordan is seeking to phase down the use of dental amalgam in a phased manner, the Jordanian Ministry of Environment addressed all relevant authorities in dentistry to work on the phase-down of using dental amalgam and move towards the use of Non-Mercury Alternatives.

The Jordanian Dental Association and the Ministry of Health were addressed by the Ministry of Environment to do so, in addition to universities that teach dentistry, so that students will be taught the alternative non-mercury materials used in dental fillings instead of the dental amalgam, where Ministry of Environment will support the efforts to accelerate the phase-down of dental amalgam containing mercury.

It is worth to be mentioned that Asia-Pacific the world's largest region both in population and in size is going through the transition to mercury-free dentistry. In Asia are seven of the 10 most populous nations on earth, where Asia is both large population states but also small population states, particularly in the Pacific Island region. Among these diverse countries, cultures, and governments, intense interest exists in a rapid transition to mercury-free dentistry among which is Jordan.

Also, it is very important to benefit from the experiences of the countries of Asia and the Pacific in this field, for example, Asians and Pacific Islanders favor the transition to mercury-free dentistry for many reasons, including:

- Fish is a major source of food, and dental mercury methylation in the fish can permanent damage the developing brains of children eating the fish, or the developing brains of babies nursing from women eating fish, or in the womb from pregnant women eating fish.
- Waste facilities for dental amalgam are not well-developed in Asia, and it would be foolhardy to spend money on waste management instead of on amalgam elimination.
- A lack of storage space exists for island states – again, making the focus source reduction, that is amalgam elimination.
- In a workplace, the risk from mercury vapors is substantial to dental workers in amalgam-using clinics and hospitals.

- Dental amalgam is not modern dentistry; it is tooth unfriendly, requiring removal of good tooth matter. The alternatives like composite and ionomers are modern, non-polluting, and tooth-friendly.

Therefore, the use of non-mercury alternatives instead of dental amalgam will eliminate the source of this pollution, producing both environmental and health benefits, for example, regarding the end of amalgam use for the nation, Nepal, Philippines, Bangladesh, Japan, and New Caledonia made great efforts some are in the phase-out of dental amalgam use or stopping teaching amalgam to dental students or and others are in banning amalgam use or in stopping use of amalgam for children, pregnant women, and breastfeeding women. On the other hand, some countries made great efforts regarding the end of amalgam use in key sectors, such as Pakistan, Vietnam, Indonesia, India, and Bangladesh.

In this regard, the important role of the local community in assisting in these efforts cannot be forgotten. Therefore, the Jordanian Ministry of Environment works in cooperation with the NGOs to achieve its objectives in the transition to Mercury-Free Dentistry. Also, the activities of civil society in this regard can also be found in many countries, such as India, Vietnam, and Bangladesh.

We're looking forward to continuing working with you for the benefit of protecting our environment and health from exposure to different sources of mercury including dental amalgam mercury-containing.

Sincerely yours,

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[1] Has the implementation of the Minamata convention had an impact on the practice of operative dentistry in Jordan?, <https://pubmed.ncbi.nlm.nih.gov/30282511/>

[2] Minamata Initial Assessment, <http://www.mercuryconvention.org/Portals/11/documents/MIAs/Jordan-MIA-2018.pdf>, page 19





REPUBLIC OF MOZAMBIQUE  
MINISTRY OF LAND AND ENVIRONMENT  
NATIONAL DIRECTORATE OF ENVIRONMENT

To:  
Minamata Convention Secretariat, [mea\\_minamatasecretariat@un.org](mailto:mea_minamatasecretariat@un.org)  
Mr. Takafumi Anan, [takafumi.anan@un.org](mailto:takafumi.anan@un.org)  
Geneva, Switzerland

Ref.: /MTA/ /DINAB/GDN/21 Data: 29.01.2021

SUBJECT: Measures to Phase Down Amalgam Use and to Transition to Mercury-Free Dentistry

Dear Sir

Mozambique adopted and signed the Minamata Convention on Mercury at the Plenipotentiary Conference, in Minamata, Kumamoto, Japan, on 10 October 2013. The Ministry of Land and Environment (MTA) is the entity responsible for the implementation of this Convention and since then it has been making efforts to ratify this Convention, as for example the Preparation of the Initial Assessment of Minamata (MIA) and the Action Plan for the Artisanal and Small Gold Scale Mining sector (NAP). This project "*Measures to reduce the use of amalgam and make the transition to dentistry without Mercury*" will assist our government in the process of ratifying of the convention.

Mozambique supports a transition to Mercury-Free Dentistry. Amalgam use needs to phase down, because: (1) it is a major Mercury pollutant, (2) the costs of Mercury waste management are too high, (3) Dental Mercury poisons the food children eat, (4) amalgam is a health risk to children, pregnant women, and breastfeeding women, and (5) placing amalgam is a workplace risk to dentists and dental workers; and (6) the alternatives are available, modern, and superior.

Our country has taken the following measures to phase down the use of Dental Amalgam and initiate the transition to Mercury-Free Dentistry:

- Cooperation with the World Health Organization (WHO), as well as other NGOs involved in this process, for the protection of human health in relation to Mercury and

- the inclusion in those of the country in the roles played under the relevant multilateral environmental agreements;
- Elimination of the use of Dental Amalgams and appliances with Mercury in the health sector;
  - Conducting awareness campaigns for all target groups in relation to the danger that Dental Amalgam poses to health and the environment;
  - Strengthening of waste management units contaminated by Mercury in rural and urban communities, with a view to preventing exposure to Mercury of vulnerable populations, especially pregnant women and children.

Please do not hesitate to contact us, whose address and contact are bellow for correspondence.

MS Laura Daniela Ferrão Noé Nhantumbo  
National Focal Point of Minamata Convention on Mercury  
[lauradaniela2014.ld@gmail.com](mailto:lauradaniela2014.ld@gmail.com)  
Ministry of Land and Environment  
National Agency for the Quality Control-AQUA  
Rua da Resistência, nº , P.O. BOX 2020  
Tel/Fax. +258 21466245; Cell phone +258 82 4819520/+258 848655480  
Maputo, Mozambique

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Rua da Resistência 1746/47 [mta@mta.gov.mz](mailto:mta@mta.gov.mz) Maputo



Ref: 10

Government of Nepal

## Ministry of Health & Population



Phone: 4

262987  
262590  
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262935  
262862

Ramshahpath, Kathmandu  
Nepal

Date : 21 July 2020

To,

The Secretariat of the Minamata Convention  
Email: mea-minamatasecretariat@un.org

and

Mr. Takafumi Anan, Associate Expert  
(Email: takafumi.anan@un.org)

### Subject: Submission of the Information

Dear Sir and Madam,

With reference to request from Center for Public Health and Environmental Development, Kathmandu Nepal, the submission from Government of Nepal, Ministry of Health and Population (MOHP) on different dates on Dental Amalgam and other mercury containing equipment. The attached copies attached into the **Annex 1** MOHP letter and **Annex 1A. Notary Translation and Annex 2** GON/MOHP Decision in and **Annex 2(A) English Translation**)

Thanking you.  
With best regards

**Bijaya Kranti Shakya**  
Senior Public Health Officer

CC :  
WHO, Country Office  
Kathmandu, Nepal

Center for Public Health and Environmental Development  
Kathmandu Nepal



# Annex 1. GON, MOHP decision on Dental Amalgam



**नेपाल सरकार**  
**स्वास्थ्य तथा जनसंख्या मन्त्रालय**  
(गुणस्तर मापन तथा नियमन महाशाखा शाखा)

२०६२/०१/०१  
२०६२/०१/०२  
२०६२/०१/०३  
२०६२/०१/०४  
२०६२/०१/०५  
२०६२/०१/०६

प्राप्त पत्र संख्या :-  
पत्र संख्या ००६२/०६  
समाप्ति नं. :- ००/०२



रामबाबुपुत्र,  
काठमाडौं, नेपाल ।  
मिति :- मिति : २०७६/०५/१५

**विषय :-** मर्करीयुक्त उपकरणहरू र डेन्टल अमलगम सम्बन्धमा ।

श्री वन तथा वातावरण मन्त्रालय, सिंहदरबार, काठमाडौं ।  
श्री सामाजिक विकास मन्त्रालय, सातौं बटौ प्रदेशहरू ।  
श्री स्वास्थ्य सेवा विभाग, टेकु ।  
श्री औषधी व्यवस्था विभाग, बिजुलिबजार ।  
श्री आयुर्वेद तथा वैकल्पिक चिकित्सा विभाग, टेकु ।  
श्री नेपाल डेन्टल एसोसिएसन, बालकुमारी, ललितपुर ।  
श्री एसोसिएसन अफ प्राइमेट डेन्टल इन्सिट्यूट्स अफ नेपाल (अफिन), ज्वागल ललितपुर ।  
श्री त्रिभुवन विश्व विद्यालय, काठमाडौं ।  
श्री काठमाडौं विश्व विद्यालय, धुलिखेल ।  
श्री पाटन स्वास्थ्य विज्ञान प्रतिष्ठान, ललितपुर ।  
श्री वि.पि.कोइराला स्वास्थ्य विज्ञान प्रतिष्ठान, धरान ।  
श्री प्राविधिक शिक्षा तथा व्यावसायिक तालिम परिषद (CTEVT) ।

उपरोक्त सम्बन्धमा मर्करीयुक्त उपकरण र डेन्टल अमलगम सम्बन्धमा तपसिल बमोजिमको गर्ने गराउने निर्णयहरू नेपाल सरकार (मानविक उपप्रधानमन्त्री एवं स्वास्थ्य तथा जनसंख्या मन्त्रीस्तर) को मिति २०७६/०५/०४ को निर्णयानुसार अनुसूच छ ।

१. गर्भवती तथा स्तनपान गराई रहेको महिला तथा १५ वर्ष मुनिका बालबालिकाहरूमा मर्करी डेन्टल अमलगमको प्रयोग पूर्णतः प्रतिबन्ध लगाउने ।
२. अन्य उमेरको हकमा विकल्प भएमा (मर्करी डेन्टल अमलगमको प्रयोगमा) पाँच वर्ष भित्र प्रतिबन्ध गर्ने ।
३. दन्त चिकित्सा अध्ययन, अध्यापन गराउने विश्वविद्यालय तथा प्रशिक्षणहरूलाई मर्करी डेन्टल अमलगमको प्रयोगबाटै पाठ्यक्रम परिमार्जन गर्ने ।
४. प्रयोगात्मक अभ्यासमा मर्करी डेन्टल अमलगमको प्रयोग प्रतिबन्ध गर्ने ।

  
**विजय कान्त शास्त्री**  
**वरिष्ठ जनस्वास्थ्य अधिकृत**

**Annex 1:** Ministry of Health and Population letter in Nepali Language (Letter about Dental Amalgam) dated September 01, 2019 (2076/05/15 BS)



## Annex 1 (A). NOTARY TRANSLATION of GON, MOHP decision on Dental Amalgam

२५५



Office Seal

Government of Nepal

### Ministry of Health and Population

(Quality Standard and Regulation Division)

Ramchuh Path  
Kathmandu, Nepal

Phone/Fax:  
42627796  
42627797  
42627798  
42627799  
42628662  
4221589

Received Ref. No.:  
Ref. No.: 076/77  
Dispatch No.: 02/72

Date: 2076/05/15 BS  
(September 01, 2019 AD)

#### Subject: Regarding Mercury based Equipments and Dental Amalgam

M/s Ministry of Forest and Environment, Singhdurbar, Kathmandu  
M/s Ministry of Social Development, all seven provinces  
M/s Department of Health Services, Teku  
M/s Department of Drug Administration, Bijulibajar  
M/s Department of Ayurveda and Alternative Medicine, Teku  
M/s Nepal Dental Association, Balkumari, Lalitpur  
M/s Association of Private Health Institution Nepal (APHIN), Jwagal, Lalitpur  
M/s Tribhuvan University, Kirtipur  
M/s Patan Academy of Health Sciences, Lalitpur  
M/s B.P. Koirala Institute of Health Sciences, Dharan  
M/s Council of Technical Education and Vocational Training (CTEVT)

With reference to above mentioned subject, it is hereby requested as per the decision of Government of Nepal (Hon. Deputy Prime Minister & Minister for Health and Population Level) dated 2076/05/04 BS (August 21, 2019 AD) to implement and make to implement the following decisions regarding Mercury based Equipments and Dental Amalgam.

1. Complete ban the use of mercury dental amalgam in pregnant and breast feeding women and children below 15 years.
2. Ban the use of (Mercury Dental Amalgam) in other age group of people within five years upon available of alternatives.
3. Amend the curriculum from the use of mercury dental amalgam itself of Institution providing dental health education under Universities and Academies.
4. Ban using of mercury dental amalgam in practical exercise.



Sd/  
Bijay Kranti Shukya  
Senior Public Health Officer



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

MAY 14 2020

**ADMINISTRATIVE ORDER**

No. 2020 - 0020

**SUBJECT: Guidelines on the Phase – Out of Mercury Use in Dental Restorative Procedures**

**I. BACKGROUND / RATIONALE**

With the enactment of RA 11223 also known as the Universal Healthcare Law, the Department of Health is committed to ensure that every Filipino citizen is entitled to healthy living, working and schooling conditions and access to comprehensive set of health services.

The World Health Organization (WHO) reported that dental caries is a major public health problem where 60-90% of school children and nearly 100% of adults have dental cavities globally. Although the Department of Health and other concerned stakeholders have consolidated efforts to promote oral health and prevent dental caries, dental restorations are still necessary in most people.

While dental amalgam is still used in several countries including the Philippines, concerns were raised on the potential health and environmental impacts of mercury use due to its bio accumulative and persistent properties.

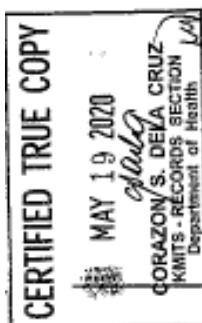
In October, 2013, the Philippines signed the global-legally-binding treaty on mercury. The Minamata Convention on Mercury provides controls and reductions across a range of products, process and industries where mercury is used, released or emitted.

In line with this, the Department of Health in coordination with concerned government agencies shall adopt a **phase-out** policy of dental amalgams.

**II. OBJECTIVES**

This Order aims to provide the guidelines on the phase-out of mercury use in dental restorative procedures. Specifically, it seeks to:

1. Provide a comprehensive policy direction in the phase-out of dental amalgams in the country.
2. Develop guidelines for the phase – out of the importation, manufacture, distribution/offer for sale and use of dental amalgams in the country.
3. Establish health and safety guidelines in the handling, use and disposal of dental amalgams among dental workers and students including patients.



Building 1, San Lazaro Compound, Rizal Avenue, Sta. Cruz, 1003 Manila • Trunk Line 8651-7800 local 1108, 1111, 1112, 1113  
Direct Line: 8711-9502; 8711-9503 Fax: 8743-1829 • URL: <http://www.doh.gov.ph>; e-mail: [fdouque@doh.gov.ph](mailto:fdouque@doh.gov.ph)

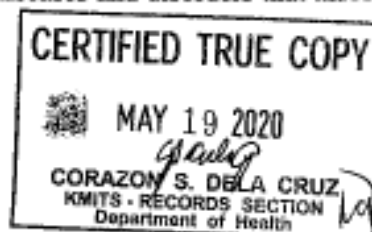
4. Educate and promote awareness among consumers and other concerned stakeholders on dental restorative materials.
5. Identify measures to strengthen strategies on dental carries prevention and oral health promotion.

### III. SCOPE

These guidelines shall cover the phasing-out on the importation, distribution, manufacture, storage, transport, handling, use (including dental schools and research) and disposal of dental amalgams in the Philippines.

### IV. DEFINITION OF TERMS

1. Alternative dental restorative materials - refers to materials used as alternates for dental amalgam.
2. Dental amalgam (commonly known as "silver fillings") – is used to repair decayed or broken teeth generally made up of mercury, silver and tin, with small amounts of copper and zinc.
3. Dental amalgam capsule – a capsule that contains silver alloy, mercury, a pestle and a plastic bubble.
4. Distributor/importer/exporter – means any establishment that imports or exports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets.
5. Exposure – amount of chemical that is available for absorption into the body through possible routes of entry into the body (i.e. inhalation, ingestion and skin absorption).
6. Importation - means the entry of products or substances into the Philippines (through the seaports or airports of entry) after having been properly cleared through or still remaining under customs control, the product or substance of which is intended for direct consumption, merchandising, warehousing, or for further processing.
7. Manufacturer – in relation to a health product, means an establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formulation, filling, packing, repacking, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution.
8. Oral health – shall mean being free of chronic mouth and facial pain, oral and throat cancer, oral sores, birth defects such as cleft lip and palate, periodontal (gum) disease, tooth decay and tooth loss and other diseases and disorders that affects the mouth and oral cavity.

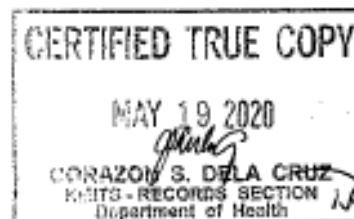


9. Precautionary principle approach - is a strategy for approaching issues of potential harm when extensive scientific knowledge on the matter is lacking.
10. Registration – the process of approval of an application to register health products prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer and where applicable the use, testing, promotion, advertisement, and and/or sponsorship of health products.
11. Retailer – any establishment, which sells or offers to sell any health product directly to the public.
12. Treatment, Storage and Disposal (TSD) Facility – means the facility where hazardous wastes are transported, stored, treated, recycled, reprocessed, or disposed of.
13. Waste generator – means a person who generates or produces hazardous waste through any institutional, commercial, industrial or trade activities.
14. Waste transporter – a person, corporation or juridical person registered to transport hazardous wastes.
15. Waste treater – means a person, corporation or juridical person registered to treat, store, recycle or dispose hazardous wastes.

## V. IMPLEMENTING GUIDELINES

### A. Proper Use / Storage

1. The use of dental amalgams under this Order shall be specific for dental restoration, use in dental schools and research purposes only. The distribution, use, handling, retail and re-sale of dental amalgam capsules shall not be used for purposes other than which is allowed under this Order.
2. Dental amalgam capsules in combined, pre-dosed encapsulated form containing at most 50% mercury by weight, for single use only, shall be allowed for use of government dental units, the local dental schools and private industrial dental clinics during the phase - out period only.
3. Dental amalgam filling shall not be given to pregnant women, children under the age of fourteen (14), breastfeeding mothers and persons with compromised renal and immune systems in consonance with the precautionary principle approach.
4. Distributors/importers/exporters, manufacturers, retailers, waste generators and users (dental practitioners, dental schools and researchers) shall phase-out dental amalgam in accordance with this Order.





5. The importation of liquid mercury and dental amalgam capsules for use in dental restorative purposes shall not be allowed upon the effectivity of this Order.
6. The Food and Drug Administration (FDA) shall regulate dental amalgam capsules in combined, pre-dosed encapsulated form, for single use only in accordance with an agreed timeline and supply reduction guidelines within the prescribed period.
7. Under this Order, the phase-out period shall be within three (3) years from effectivity after which the use of dental amalgam in the country shall no longer be allowed.

**B. Proper Disposal**

1. The management of dental amalgams in dental clinics and dental schools shall be collected, stored and disposed in accordance with the existing rules and regulations of the Environmental Management Bureau (EMB) of the Department of Environment and Natural Resources (DENR) on the disposal of hazardous waste.
2. The waste shall be collected and disposed of through an accredited waste transporter and TSD facility.

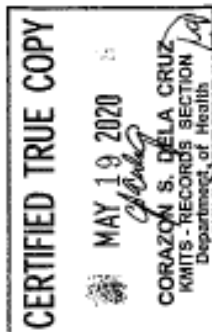
**C. Institutional Mechanism**

1. Strengthening of the operational structure for the implementation of the guidelines on the importation, handling, use and disposal of dental amalgams shall be achieved within the existing public health programs at different levels of governance through multi-sectoral cooperation / collaboration.
2. A reporting mechanism shall be developed through the Inter-Agency Committee on Environmental Health (IACEH) Chemical Safety and Health Sector to discuss issues and concerns of relevant stakeholders on the implementation of this Order. An Inter-Agency Technical Working Group (IATWG) shall be created for monitoring and evaluation of the implementation of the provisions of this Order during the phase out period.
3. Consumer Protection Groups, Civil Society Organizations (CSOs) and the academe may provide assistance to government agencies in the dissemination and implementation of this Order.

**D. Capacity Building**

1. Health and safety trainings /seminars on the handling, use and disposal of dental amalgams shall be developed and conducted to educate dental health workers, dental school students and patients.

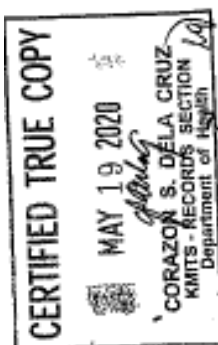
Dentists and dental students who are intending to use dental amalgam capsules shall be protected from unnecessary exposure to mercury through training and the proper use of Personal Protective Equipment.



## VI. ROLES AND RESPONSIBILITIES

1. The Department of Health (DOH) shall:
  - a. Strengthen the National Oral Health Program;
  - b. Phase-out the use of dental amalgams in all health care facilities in accordance with the set timelines;
  - c. Develop and conduct training programs on the health effects of mercury and use of mercury – free alternatives for DOH healthcare personnel;
  - d. Raise public awareness on the effects of mercury to human health and environment through the Health Promotion and Communication Service (HPCS); and
  - e. Integrate the existing funds and/or earmark funds for the implementation of this Order.
2. The Food and Drug Administration (FDA) shall:
  - a. Issue an advisory on the phase – out of dental amalgams;
  - b. Stop the registration of dental amalgams during the phase out period;
  - c. Perform post – market surveillance of dental amalgams in the market; and
  - d. Issue regulatory actions to distributors, retailers, importers, exporters, who sell dental amalgams after the phase – out period.
3. The Department of Environment and Natural Resources-Environmental Management Bureau (DENR-EMB) shall:
  - a. Issue an advisory on the proper storage and disposal of dental amalgams;
  - b. Prescribe regulation and licensing requirements for the storage and disposal of dental amalgams; and
  - c. Conduct monitoring to ensure that the disposal of dental amalgams shall be in accordance with the existing policies and guidelines.
4. The Department of Labor and Employment (DOLE) shall prescribe the rules and regulations for occupational safety and health standards for dental clinics.
5. The Department of Finance – Bureau of Custom (DOF-BOC) shall:
  - a. Implement the ban on the importation of dental amalgam in the country;
  - b. Provide a report on the volume of importation of mercury and dental amalgam capsules that have entered the country; and
  - c. Enforce this Order and other proposed guidelines, as necessary, regarding the importation of mercury in the Philippines during the phase – out period.
6. The Department of the Interior and Local Government (DILG) shall:
  - a. Issue and disseminate this Order and other guidelines/memoranda to the Local Government Units relative to this Order; and
  - b. Serve as the oversight body to the LGUs responsible for monitoring their compliance to these guidelines and other issuances pertinent to this Order.

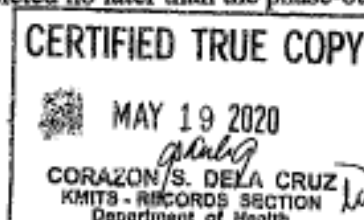
The Department of Trade and Industry – Bureau of Philippine Standards (DTI-BPS) in cooperation with the Department of Health, shall issue standards needed for alternative dental restorative materials as Philippine National Standards.



8. The Department of Science and Technology (DOST) in coordination with Department of Health and the Philippine Dental Association, shall lead the research and development efforts on mercury – free alternatives such as resin composites to dental amalgam, conduct further studies on its safety profile and durability, and encourage the search for new and better alternative materials.
9. The Department of Education (DepEd) shall develop and implement strategies to prevent dental caries and dental diseases, promote oral health and the use of mercury free alternatives for dental restorative procedures in school children.
10. The Commission on Higher Education (CHED) shall standardize the teaching and training on the use of alternatives to dental amalgam in the dentistry curriculum in collaboration with the Philippine Association of Dental Colleges (PADC).
11. The Professional Regulation Commission (PRC) shall review and revise the licensure examination for dentist, particularly the practical phase to replace dental amalgam with composite restoration and other available alternatives, under the Board of Dentistry, during the phase - out period.
12. The Philippine Dental Association (PDA) shall:
  - a. Develop clinical guidelines and best practices for the safe use, handling and disposal of dental restorative materials in collaboration with government agencies;
  - b. Formulate best practice guidelines on the use, handling, storage and disposal of alternatives to dental amalgam; and
  - c. Disseminate information materials to patients on oral health programmes and safety of dental restorative materials.
13. The Civil Society Organizations shall:
  - a. Support the campaign of the government on the phase – out of dental amalgam;
  - b. Conduct awareness campaigns on the effects of mercury on health as well as the environmental and health benefits of the phase – out of dental amalgam.

## **VII. TRANSITORY PROVISION**

1. Immediately upon the effectivity of this Order, the following shall be implemented:
  - a. Ban on the importation of liquid mercury for use in dental restorative procedures and dental amalgam and its capsules;
  - b. Ban on the use of dental amalgams and its capsules for children fourteen (14) years old and below, pregnant women and nursing mothers.
2. The ban on the use of existing dental amalgams / capsules for dental restoration procedures in dental clinics and schools shall be carried out after three years from the effectivity of this Order.
3. Proper storage and disposal of all dental amalgam capsules in the country through an accredited TSD facility shall be completed no later than the phase-out period of three (3) years.



*[Handwritten signature]*

## **VIII. BUDGET AND FINANCING**

The concerned national agencies shall allocate a corresponding yearly budget for the implementation of this Order.

## **IX. SEPARABILITY CLAUSE**

In the event that any provision or part of this order is declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected by such declaration shall remain and effective.

## **X. PENALTY CLAUSE**

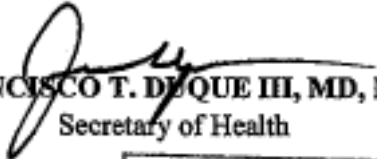
Any person or entity that violates any of the provisions of these guidelines shall be subject to applicable fines and penalties as provided for in Republic Act 9711 "Food and Drug Administration Act of 2009", Republic Act No. 7394 "Consumer Act of the Philippines", and Republic Act No. 6969 "Toxic Substances and Hazardous Wastes and Nuclear Wastes Control Act of 1990" and its corresponding implementing rules and regulations and other existing pertinent laws, rules and regulations.

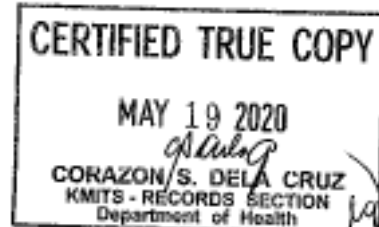
## **XI. REPEALING CLAUSE**

Provisions of Administrative Order No. 2008-0021 and other issuances or parts thereof that are inconsistent with the provisions of this Administrative Order are hereby repealed, amended or modified accordingly.

## **XII. EFFECTIVITY**

This order shall take effect fifteen (15) days after posting in the official website, publication in a newspaper of general circulation and submission of a copy hereof to the Office of the National Registry of the University of the Philippines Law Center.

  
**FRANCISCO T. DEQUE III, MD, MSc**  
Secretary of Health





No. 0304/ ๗๐๖๒



Pollution Control Department  
92 Soi Phahon Yothin 7, Phahon Yothin Rd.,  
Phayathai, Bangkok 10400 THAILAND  
Tel: 66 2298 2422 Fax: 66 2298 5393

๑๐ June B.E. 2564 (2021)

Dear Madam,

**Subject:** Decision on dental amalgam

In reference to the decision MC-3/2 on dental amalgam, the Conference of the Parties, among other things, encourages parties to take more than the two required measures in accordance with part II of annex A to the Convention to phase down the use of dental amalgam, and requests the secretariat to collect information on the implementation of any such additional measures taken by parties.

In response to such decision, the Pollution Control Department of Thailand as the national focal point to the Minamata Convention on Mercury would like to provide the following information:

1. Preparations for phasing down dental amalgam.

Thailand has prepared relevant information for phasing down dental amalgam as follows:

1.1 Data from the study on the situations of dental fillings, health risks, and the management of waste contaminated with amalgam in the Ministry of Public Health's hospitals (Attachment No. 1)

1.2 Draft conceptual note on the Stakeholder mapping GEF Dental Amalgam Project (Attachment No. 2)

1.3 Results from the Technical Seminar and Public Hearing on Technical Conclusions on the Health Effects of Amalgam Use, 20 December 2018, Centara Grand Hotel at Central World, Bangkok, Thailand organized by the Dental Association of Thailand (Attachment No. 3)

2. Additional measures to reduce the use of amalgam as described in Annex A, Part II.

Thailand has already applied measures (v) and (ix) under the Annex A, Part II and informed the Secretariat when Thailand had submitted the accession instrument to the Convention. However, as of now, Thailand has also applied more measures as follows:

2.1 Measure (i)...

2.1 Measure (ii) Setting national objectives aiming at minimizing its use

2.2 Measure (iii) Promoting the use of cost-effective and clinically effective mercury free alternatives for dental restoration

2.2.1 Developing the (draft) guideline on the dental restoration of alternative materials in pregnant woman and children under 6 years old.

2.2.2 Developing the proposal on Stakeholder Mapping GEF Dental Amalgam as a cooperative project between environmental and public health sectors and WHO to be granted by the Global Environment Facility.

2.3 Measure (v) 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.

2.4 Measure (vii) Restricting the use of dental amalgam to its encapsulated form.

2.4.1 Only limit the use of dental amalgam to its encapsulated form.

2.4.2 Drafting the (Draft) Notification of the Ministry of Public Health on defining the use of dental amalgam product containers and prescribing dental amalgam products packaged in tablet and powder forms as prohibited medical device for importation.

2.5 Measure (ix) Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.

2.5.1 Providing the manual on the use and management of waste dental amalgam in dental clinics.

2.5.2 Publishing the posters of the management of waste dental amalgam in dental clinics to be disseminated to dental professionals.

Please be assured of our full cooperation.

Yours sincerely,



(Mr. Athapol Charoenshunsa)  
Director General  
Pollution Control Department

Enclosure: as stated

Executive Secretary of the Minamata Convention  
International Environment House 1  
11-13 chemin des Anémones, 1219 Châtelaine, Geneva, Switzerland  
MEA-MinamataSecretariat@un.org

## A study on the situations of dental fillings, health risks, and the management of waste contaminated with amalgam in the Ministry of Public Health's hospitals

### Objectives

To carry out the study on the utilization situations of dental fillings and alternatives, the dental personnel behaviors, the management of dental amalgam waste, and the awareness on the Minamata Convention on Mercury of personnel in hospitals under the Ministry of Public Health.

### Methodology

1. Retrospective descriptive study was conducted by using the questionnaires survey in 959 central, general, community and academic hospitals under the Ministry of Public Health.
2. Duration of information collection was from December 2018 to July 2019.
3. Sample size was calculated by method of Krejcie & Morgan (1970) at 95% confidence level.

### Results

1. **Introduction:** 277 hospitals were participated in questionnaires survey. 84.8% of most respondents to questionnaires were dentists. 11,746 patients were the average patients who received the dental services in 2018.
2. **Dental fillings:** 2,897 patients or 24.7% were came to fill their teeth by dental amalgam fillings of 28.5% and other fillings of 71.5%. 95.7% of amalgam filling materials using in most hospitals were in its encapsulated form. 98.6% and 81.6% of alternative filling materials were composite resin and glass ionomer, respectively.
3. **Prevention activities:** Hospitals conducted the teeth decay prevention activities or programme in every age span coverage in which 53.4% in child age, 17.7% in school age, 11% in working age, and 17.7% in old age.
4. **Health risks protection in dental personnel:** In case of using the protective equipment, the 92.5% and 91.8% of personnel were wearing gloves and masks between dental services, respectively. 47.3% of dental personnel were trained about mercury and amalgam. Hospitals also prevented the mercury releases by 68.2 % of using covered boxes onto the amalgam mixers, 10.9% of using a separated room for mixing amalgam, and 23.5% of mercury accumulation monitoring in dental personnel.



5. **Waste amalgam management:** Most of amalgam scraps were sealed in closed containers in which 73.8% were stored under water and 71.9% were safe. Capsule peels had segregated as 73% of hazardous wastes, 16.5 % of infectious wastes and 8.2 of solid wastes, respectively in which 47.2 % were treated by private waste processors. Cottons and gauzes that contaminated with amalgam were segregated into 77.2% of infectious wastes, 15.7% of hazardous wastes and 5.2% of mercury hazardous wastes, respectively in which 69.7% were treated by private waste processors. There was 4.7% of mercury monitoring in wastewater from the dental service rooms.
6. **Awareness of Minamata Convention on Mercury:** There was 49.8% of hospitals that aware about the Minamata Convention in which 52.3% were dentist and 31% were dental personnel.

### Conclusion

1. The decreasing trend of amalgam filling materials using was in line with the increasing trend of alternative filling materials (composite resins and glass ionomers) using in 2015 – 2018.
2. In case of health risk protection from amalgam using, there were the prevention of mercury diffusion in most hospitals. However, even there was the sound collection of amalgam wastes; not all of them were properly treated. Also there was lack of proper mercury monitoring in discharged water from dental service rooms. The awareness of Minamata Convention in the dental personnel was still limited.
3. Recommendations include the outreach programme of Minamata Convention in order to promote more understanding; safe practices of sound dental amalgam utilization; capacity building of dental personnel in using the alternative filling materials; enhancement of the more effective teeth decay prevention programme in every age span in order to reduce needs of dental filling in long term period; and the development of management mechanism/system of waste contaminated with amalgam.

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Source: Bureau of Dental Health, Department of Health, Ministry of Public Health



Stakeholder mapping  
GEF Dental Amalgam Project

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#### Index of global stakeholders

- WHO CC's, WHO Oral Health Programme Collaborating Centres
- FDI; FDI World Dental Federation and its membership
- IDM; International Association of Dental Manufacturers and its membership
- IADR; International Association for Dental Research and its membership
- ADEAP, ADEE, IFDEA; Associations for Dental Education at global and regional levels and its membership
- Academia; including but not limited to universities and institutions of higher education and International NGOs

#### 1. Knowledge management

Output Standards, technical guidance and tools produced that enable the early implementation of the provisions of the Minamata Convention related to the phase down of the use of dental amalgam, and relevant decisions taken by the Conference of the Parties.

Project main activities	Project sub-activities
1. Conduct situation assessment and inventory of trade, supply, regulation and use of dental amalgam & quality mercury free materials	
2. Document good practice examples and demonstrate the feasibility of voluntary implementation	
3. Produce recommendations on quality mercury free products and processes according to the best knowledge available	<ul style="list-style-type: none"> <li>- Produce recommendations on the selection and use quality mercury free products and processes for dental caries management based on independent experts review process that draws upon existing EU / Member States experiences and reports.</li> <li>- Produce recommendations based on intercessional work of technical working groups</li> </ul>

Project main activities	Project sub-activities
	(Minamata and other relevant areas of work) for the best available techniques and best environmental practices to reduce and monitor emissions and releases of dental amalgam waste into air, land, soil, and water, as well as similar practices that could be applied to quality mercury free products as a part of multipollutant control strategy
4. Deliver communication strategy, and accompanying products and resources	<ul style="list-style-type: none"> <li>- Develop communication strategy, with products and resources; info – fact sheets, developing key global messages, coordination of communications with and across project countries, linkage with Global Mercury Partnership communication strategies and plans</li> </ul>
5. Develop standardized assessment tools and protocols for environmentally sound waste management of dental amalgam	<ul style="list-style-type: none"> <li>- Identification and selection criteria of health / dental facilities for environmentally sound waste management of dental amalgam waste</li> <li>- Under UNEP guidance, develop a standardized assessment tool and protocol for the selection of dental amalgam separators referring to manufacturer products specifications and requirements, and relevant information including threshold values for releases to air, land, soil and water;</li> </ul>

## 2. Multisectoral cooperation

Output Multisectoral cooperation and actions to strengthen health systems in support of Universal Health Coverage to achieve socio-economic, environmental and public health benefits in 3 countries

Project main activities	Project sub-activities
1. Set up national mechanisms to coordinate multisectoral actions	
2. Map financing of oral health services	<ul style="list-style-type: none"><li>- Collect data on the total expenditures and investment in oral health services</li><li>- Identify (if necessary develop) protocol and assessment tool for mapping of financing of oral health services in project countries including public and private sectors;</li><li>- Policy review and analysis of: i. insurance policies and programmes that favor dental amalgam use over mercury-free dental restoration, and ii. insurance policies and programmes that favor the use of quality alternatives to dental amalgam for dental restoration; in both public and private sectors.</li></ul>
3. Identify active oral health workforce stock	<ul style="list-style-type: none"><li>- Collect data on size composition and distribution of oral health workforce using WHO National Health Workforce Accounts</li><li>- Develop a series of (country-specific) health workforce education policy questions to guide and inform the shift from dentist-centric approach to population health needs approach;</li></ul>
4. Reorient health workforce education and training in support of population health needs approach	<ul style="list-style-type: none"><li>- Analysis of national education plans for oral health workforce, and the alignment with national health plans and national health workforce plans and strategies</li></ul>

Project main activities	Project sub-activities
	<ul style="list-style-type: none"> <li>- Hold regional education meetings to host deans of oral health education institutions to examine convergence of accreditation standards and population health needs approach.</li> </ul>
5. Strengthen the business and regulatory environment for accelerating early implementation	<ul style="list-style-type: none"> <li>- Identify (if necessary develop) a standard protocol and tool for mapping and assessment of the business and regulatory environment to medical devices with focused attention on materials for dental caries management;</li> <li>- Recommendations for improving and strengthening business and regulatory environment for accelerating early implementation of the use of phase down of dental amalgam.</li> </ul>

### 3. Environmentally Sound Lifecycle Management

**Output** Regulatory efforts to restrict the use of dental amalgam to its encapsulated form, and to promote the use of best environmental practices to reduce releases of mercury and mercury compounds to air, water, soil and land in 3 countries

Project main activities	Project sub-activities
1. Reinforce regulation to restrict the use of dental amalgam to its encapsulated form, and its diversion into other sectors	<ul style="list-style-type: none"> <li>- Conduct national situation assessment and inventory of trade, supply, regulation and use of dental amalgam &amp; quality mercury free materials</li> </ul>
2. Selection, installation, maintenance of dental amalgam separators, and management and disposal of dental amalgam waste at selected sites	<ul style="list-style-type: none"> <li>- Identify health / dental facilities</li> <li>- Select dental amalgam separators using standardized assessment tool and protocol (ref doc. output 1)</li> </ul>
3. Strengthen waste management mechanisms and processes at selected sites	



#### 4. Sustainability

Output Project monitoring and evaluation and reporting to inform equitable and sustainable phase down of the use of dental amalgam

Project main activities	Project sub-activities
1. Project monitoring and evaluation	<ul style="list-style-type: none"><li>- Establish project steering committee;</li><li>- Provide for a stakeholder forum, which could share and exchange data and evidence, country case examples, and other experiences that could support the effectiveness of the project outputs and outcome;</li><li>- Identify key performance indicators for project with focused attention on multispectral sustainability and equity</li></ul>
2. Identify common elements and conditions for global scale up	<ul style="list-style-type: none"><li>- Identify common elements and conditions that create long term sustainability for phase down of use of dental amalgam based on summative outputs of 1, 2 and 3 at project country level.</li></ul>
3. Reporting on effectiveness of measures taken in countries	<ul style="list-style-type: none"><li>- Establish minimum data set which ensures compatibility and interoperability for reporting on effectiveness and challenges (Article22)</li></ul>

Technical conclusions on the health effects of amalgam usages  
By the Dental Association of Thailand

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Mercury poisoning depends on its nature, methods and the amount entering to the body. Reducing of mercury uses is beneficial to humanity not only exposure reduction, but also the environmental impact reduction. However, until now, there is *no conclusion and strong accepted scientific evidences that amalgam harms health. Dental amalgam restoration does not increase the health risks of diseases to or adverse effects to the patient bodies*. Even, it has been found that there were some specific responses (local adverse effects) and they could be easily cured.

Among pregnant women and infants, although mercury can pass through the barrier between the blood vessel and the brain, including the placenta; however, based on evidences from findings, there was no relation between mercury exposure from amalgam and the side effects during pregnancy and birth weight of an infant. It was not also found that effects on an infant from breast milk of mother who had oral dental amalgam materials. There was a few clinical studies in children under 6 years old who had oral amalgam fillings and it was not found that there was impact on the brain and nervous system development from exposure to mercury from amalgam materials. Low levels of mercury had been detected below the health hazard threshold level in children population of more than 6 years old who had oral dental amalgam materials. However, if pregnant woman has a need to restore teeth, a dentist should choose methods and materials for dental restorations by considering in some factors, such as health history e.g. blood pressure, renal function, gestational age, amalgam/material/chemical allergies history, etc. While the dental restoration in children, a dentist should consider some elements, such as health history, type of teeth (baby teeth or permanent teeth), remaining periods of the teeth in the oral cavity, teeth number to be treated, etc. Therefore, for the dental restoration in pregnant women and children, a dentist should indicate positive and negative results as well as side effects of each dental filling material for their selection.

It is acceptable that dental personnel are considered to be more exposure to mercury than the general people because of their profession. However, it was not found that there was different health effects between dental personnel and general population. Precautionary measures of mercury uses in patients should be also applied to the dental

personnel in particular mercury management in dental restoration from storage, preparation in the restoration processes, waste amalgam management, and the processes of amalgam dismantling having to be careful in every patient, including the uses of a mount water prevention rubber, coolant water, and high power suction, etc.

*"Reducing mercury consumption in response to the Minamata Convention will help in reducing mercury releases to the environment"*

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## 2021 Report from the United States of America in connection with Decision MC-3/2 of the Conference of the Parties

### Information on Dental Amalgam March 2021

Article 4, paragraph 3, of the Minamata Convention on Mercury (the Convention) requires each Party to take measures for the mercury-added products listed in Part II of Annex A in accordance with the provisions therein. Part II of Annex A currently includes the following mercury-added product: dental amalgam. According to Part II of Annex A, measures taken by Parties to phase down the use of dental amalgam shall take into account the domestic circumstances of the Party and relevant international guidance. Each Party is required to take a minimum of two of the measures listed in Annex A, Part II.

In its June 2013 submission on "Measures to Implement the Minamata Convention on Mercury Pursuant to Article 30, paragraph 4, of the Minamata Convention on Mercury," the United States indicated that it would implement at least two measures listed in part II of Annex A under the Public Health Service Act, 42 U.S.C. § 241(a), and the Clean Water Act. In particular, the United States implemented the following measures listed in Part II of Annex A:

- (i) Setting national objectives aiming at dental caries prevention and health promotion, thereby minimizing the need for dental restoration;
- (iv) Promoting research and development of quality mercury-free materials for dental restoration;
- (v) 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; and
- (ix) Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.

In addition to the above, the United States further implemented Annex A, Part II, (ix) through the U.S. Environmental Protection Agency's Memorandum of Understanding with the American Dental Association and the National Association of Clean Water Agencies to promote the use of amalgam separators and other measures to capture amalgam waste and reduce its release to water. (<http://water.epa.gov/scitech/wastetech/guide/dental/index.cfm>.)

Decision MC-3/2 (adopted by the third Conference of the Parties to the Minamata Convention on Mercury) encourages Parties to take more than the two required measures in accordance with Annex A, Part II, of the Convention to phase down the use of dental amalgam. In this same decision, the Secretariat is asked to request information from Parties on the implementation of such additional measures, and to prepare a document containing such information for consideration by the Conference of the Parties at its fourth meeting. In accordance with the Secretariat's subsequent request for such information, below please find a submission from the United States regarding the aforementioned additional measures, in support of paragraphs 1, 2, and 5 of Decision MC-3/2.



- In September of 2020, the U.S. Food and Drug Administration (FDA) issued updated “Recommendations for Certain High-Risk Groups Regarding Mercury-Containing Dental Amalgam” that called for non-mercury restorations (fillings), such as composite resins and glass ionomer cements, to be used, when possible and appropriate, in people who may be at higher risk for adverse health effects from mercury exposure.

Key among the FDA’s findings were the uncertainties about the acceptable reference exposure levels for mercury vapor (gas), the potential for mercury to convert to other mercury compounds in the body, and whether the degree of accumulation of mercury from dental amalgam results in negative (adverse) health outcomes. Although the majority of evidence suggests exposure to mercury from dental amalgam does not lead to negative health effects in the general population, little to no information is known about the effect this exposure may have on members of the specific groups who may be at greater risk to potential negative health effects of mercury exposure. For further information regarding these specific groups and more information about the recommendation, please find FDA’s Safety Communication [here](#) and its press announcement [here](#).

- In June of 2017, the Environmental Protection Agency (EPA) promulgated technology-based pretreatment standards to reduce discharges of mercury from dental offices into publicly owned treatment works (POTWs). (Dental offices discharge mercury present in amalgam used for fillings. Amalgam separators are a practical, affordable, and readily available technology for capturing mercury and other metals before they are discharged into sewers that drain to POTWs. Once captured by a separator, mercury can be recycled.) The Dental Office Category regulation, codified at 40 CFR Part 441, requires dental offices to comply with requirements based on practices recommended by the American Dental Association, including the use of amalgam separators. EPA expects compliance with this final rule will annually reduce the discharge of mercury by 5.1 tons as well as 5.3 tons of other metals found in waste dental amalgam to POTWs.

Decision MC-3/2 also calls for the Secretariat to request information from Parties related to Paragraph 7 of Article 4. The United States does not have any information to submit related to Paragraph 7 at this time.

# Amalgama Dental y Control del Mercurio

## Informe Facultad de Odontología (UdelaR)

Setiembre, 2017



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*Este documento fue elaborado en octubre de 2016 por la Facultad de Odontología de la Universidad de la República (Cátedra de Farmacología y Terapéutica, Nodo Odontología de Farmacovigilancia y Materiovigilancia). Recoge su enfoque y posición respecto al uso y control del mercurio en amalgamas dentales. Busca aportar a la difusión, capacitación y puesta en práctica de líneas de trabajo que compatibilicen la salud bucal y el control del mercurio, siguiendo los acuerdos internacionales asumidos a nivel nacional. Incluye un anexo que refiere a la seguridad de las amalgamas dentales y a los aspectos toxicológicos del mercurio.*

*El Proyecto URU/13/G32 "Gestión ambientalmente adecuada del ciclo de vida de los productos que contienen mercurio y sus desechos", implementado por el Ministerio de Vivienda, Ordenamiento Territorial y Medio Ambiente con participación del Ministerio de Salud, financiado por el Fondo para el Medio Ambiente Mundial (FMAM) a través del Programa de las Naciones Unidas para el Desarrollo (PNUD), apoya la difusión de este material con el fin de desarrollar en Uruguay las medidas contenidas en el Convenio de Minamata sobre Mercurio, vigente desde el 16 de agosto de 2017.*

*El análisis y las recomendaciones de políticas contenidas en este Informe no reflejan necesariamente las opiniones del Programa de las Naciones Unidas para el Desarrollo, de su Junta Ejecutiva o de sus Estados miembros.*



## AMALGAMA DENTAL Y CONTROL DEL MERCURIO

### 1. INTRODUCCIÓN

La amalgama dental es el material restaurador más utilizado en la historia de la Odontología. Se introdujo en Europa en 1819 por Bell, generalizándose su uso en 1826 y llegando a Estados Unidos en 1830.<sup>1</sup>

Refinadas sus características se difundió ampliamente a nivel mundial sobre todo luego de las mejoras en su composición y protocolización introducidas por J. D. Black.<sup>2</sup>

Se caracteriza por su fácil manipulación, bajo costo y predictibilidad.<sup>3</sup> No obstante ello, por poseer Mercurio en su composición ha sido cuestionada por distintos autores<sup>5</sup> y sugerida su restricción por organismos, instituciones y autoridades de diversos países llegando incluso a su prohibición en tres de ellos por razones ambientales.<sup>6-8</sup>

### 2. MERCURIO Y AMALGAMA

El mercurio no es esencial para los procesos biológicos, pero frente a la exposición y contaminación se puede acumular en los tejidos vivos pudiendo causar toxicidad<sup>9</sup> al precipitar las proteínas sintetizadas por la célula, particularmente las neuronas, e inhibir los grupos sulfidrilo de enzimas esenciales.

El mercurio de las amalgamas se encuentra como elemental (o metálico) y como mercurio inorgánico y es potencialmente de menor toxicidad que el denominado mercurio orgánico de tipo dietil, fenil y metil mercurio. El mercurio elemental contenido en la amalgama debido a la corrosión intrabucal se libera como mercurio elemental y como mercurio inorgánico.<sup>10</sup>

Los compuestos orgánicos como el metilmercurio son solubles en lípidos, son altamente difusibles a través de las membranas y se biotransforman lentamente en mercurio inorgánico. Se manejan niveles o umbrales máximos de concentración en aire ambiental. Se han detectado entre 10 y 20 nanogramos de mercurio por metro cúbico de aire (ng/m<sup>3</sup>) en el aire de zonas urbanas.<sup>12</sup>

El contenido normal de mercurio total en el organismo está entre 1 y 13 miligramos, el 10% es metilmercurio.<sup>13</sup>

La concentración urinaria de mercurio promedio en EE.UU. es de 0,72 mcg/l y la concentración sanguínea promedio 0,34 mcg/l. En Europa se encuentran valores más altos.<sup>14</sup>

Las concentraciones urinarias promedio aumentan en relación al número de superficies de amalgamas dentales. Mientras que las concentraciones sanguíneas promedio aumentan en función del consumo de pescado.<sup>15</sup>

*El valor de referencia, o valor umbral límite de la American Conference of Governmental Industrial Hygienists (ACGIH) para mercurio elemental y sus formas inorgánicas es de 0,025 mg/m<sup>3</sup>/8horas/día/5días semana.<sup>11</sup>*

Con respecto a la exposición simultánea: amalgama Hg inorgánico, alimentos Hg orgánico, existe evidencia de que la determinación del nivel de mercurio inorgánico en el plasma y en los eritrocitos es el indicador de la absorción del mercurio procedente de la amalgama y que la determinación del mercurio total en sangre incluye un 47 % de mercurio orgánico (incluso en poblaciones con baja ingesta de pescado).

El mercurio inorgánico se excreta por vía intestinal y renal (50% y 50%). El mercurio orgánico por vía intestinal. Por eso existe una fuerte correlación entre la concentración de mercurio en orina y la superficie de amalgama y por eso las concentraciones de mercurio en orina son las que se aplican como medida de exposición al mercurio de las amalgamas.<sup>15</sup>

Cifra de ingesta tolerable según la OMS: 0.23 mcg/día/kg de peso corporal (si pesa 65 kg es de 15 mcg/día). En el caso que el mercurio absorbido por una persona con 7 amalgamas fuera solamente el inorgánico (sin contemplar el de la dieta) la cifra de la OMS está muy por encima de la del mercurio que procede de la amalgama.

- Otros valores para vapor de mercurio EPA 0.3 mg/m.
- Nivel de riesgo mínimo de la ATSDR 0.2 mg/m.<sup>15</sup>

Si bien en la literatura siguen existiendo posiciones encontradas<sup>17</sup>, la posición más consolidada es que las amalgamas no ofrecerían concentraciones que fehacientemente provocaran daño físico o ambiental relevante<sup>18</sup> distintos organismos aconsejan el desestímulo de su uso (PNUMA 2007, Alianza Mundial sobre el Mercurio) como medida de control eficiente del mercurio pero con una retirada gradual de su oferta y utilización odontológica<sup>19</sup>. También la FDI en 2009 y la ADA en 2010 acompañan esta posición, basadas especialmente en sus repercusiones sobre el control ambiental del Mercurio.

Es de hacer notar que esta actitud proactiva sobre la biotolerancia debe mantenerse para todos los materiales incluyendo los materiales odontológicos más modernos (acrílatos, BIS-GMA, resinas)<sup>20</sup> los de uso médico como vacunas y antisépticos, los de iluminación, agroindustria etc.<sup>21</sup>

Un factor que complejiza el abordaje temático es el riesgo de lobby, a todo nivel, de las empresas multinacionales buscando imponer en el mercado materiales de mayor costo y que signifiquen mayor ganancia empresarial pero con la consiguiente pérdida económica para países y poblaciones.

*La relación mercurio en orina y superficie de amalgama es de 0.09 mcg/l por superficie de amalgama:*

*10 superficies de amalgama aumentan los niveles de mercurio urinario en 1 mcg Hg/l.*

*Dosis de mercurio absorbido que proviene de amalgamas:*

*2,7 mcg/día/persona con una cantidad promedio de 7,4 obturaciones.<sup>15-16</sup>*

### 3. EPISODIO DE MINAMATA

Dada su gravedad el episodio más referido de contaminación es el de la bahía de Minamata (Japón), en donde en 1956, desechos industriales de una fábrica vertidos al mar en considerables proporciones contaminaron la ictiofauna que formaba parte de la dieta de las poblaciones.<sup>22</sup>

El mercurio hallado en el lecho de ríos, mares y océanos, tiene un origen primordialmente industrial (fabricación de álcalis-cloro, ácido acético y otros) y después de su llegada como inorgánico o elemental es metilizado por los microorganismos del fondo, generando fenómenos de bioacumulación en la cadena trófica, con concentraciones proporcionalmente más altas (biomagnificación) cuanto más alto sea el lugar de la especie en dicha cadena (ej. grandes peces como atunes o tiburones). El consumo de los mismos en la dieta genera proporcionalmente más disponibilidad de mercurio que las propias amalgamas y con mayor toxicidad por su metilización.

El metil mercurio ingerido por la población que consume productos del mar se absorbe en más del 90% en el intestino.

El metilmercurio puede atravesar la placenta y acumularse en el cerebro fetal. También existe la contaminación a través de la ingestión de la leche materna. El metil mercurio es capaz de generar efectos nocivos en niños y adultos, y daños teratogénicos en mujeres embarazadas. El sistema nervioso en desarrollo de los niños es particularmente sensible al metilmercurio y los efectos adversos varían según el nivel de exposición. En el adulto una exposición importante puede ocasionar cambios de personalidad, trastornos en la audición, visión, coordinación muscular, en la memoria, deficiencia intelectual e incluso la muerte.<sup>23</sup> La Agencia de protección del medioambiente americana clasifica al metilmercurio potencialmente cancerígeno para los humanos y últimamente se le atribuyen efectos indeseables en el sistema inmunitario y cardiovascular en concentraciones bajas.<sup>24</sup>

Si bien los vertidos cloacales de restos de amalgama dental son poco significativos igualmente pueden llegar a espejos de agua y metilizarse. Para evitar esta situación se ha protocolizado claramente su control, proscribiendo el vertido al saneamiento público.

### 4. CONCENTRACIÓN DE MERCURIO EN PORTADORES DE AMALGAMA

Como se señaló si bien la amalgama no posee metil mercurio es capaz de liberar mercurio elemental o inorgánico el cual se puede incorporar al organismo. El mismo no debería superar las concentraciones estudiadas y pre establecidas. Varios artículos demuestran mayor concentración en sangre y orina de los portadores de amalgama frente a los no portadores<sup>1</sup> generando posibilidad de bioacumulación en riñón e hígado. Puede suceder la liberación del metal por acción de la masticación, bruxismo o el cepillado e incluso facilitarse por variaciones de la temperatura bucal (esto es controvertido). Muchos de los artículos que la cuestionan presentan debilidades metodológicas como por ejemplo el no contemplar las distintas vías de incorporación de mercurio en las poblaciones estudiadas, o no ilustrar estudios longitudinales prospectivos. Otros autores señalan que el número de amalgamas necesarias para superar las concentraciones de seguridad no se manejan en la consulta habitual y se está extremadamente lejos de poder alcanzarlas.<sup>2</sup>

*Límites de exposición  
segura del mercurio  
en la dieta:*

*0,1 mcg/kg/día según  
la U. S.  
ENVIRONMENT  
PROTECTION AGENCY  
(EPA).*

*0,3 mcg/kg/día según  
la U.S. AGENCY FOR  
TOXIC SUBSTANCES  
AND DISEASE  
REGISTRY (ATSDR).*

*0,43 mcg/kg/día para  
la U.S Food and Drugs  
Administration (FDA).*

*0,47 mcg/kg/día  
Organización Mundial  
de la Salud (OMS).*



La ANSM, en concordancia con un estudio epidemiológico y un meta-análisis elaborado por el *Institut National de la Santé et de la Recherche Médicale*, (INSERM)<sup>25</sup>, durante el período 2003- 2014 —coherente con el *Scientific Committee on Emerging and Newly-Identified Health Risks* (SCENIHR) en su informe sobre amalgamas dentales— ha informado que las últimas publicaciones científicas no permiten establecer una relación entre el mercurio de las amalgamas dentales y las patologías observadas del tipo neurológicas, psicológicas, psiquiátrica o nefrológicas. Desde el año 2014, el SCENIHR afirma que las amalgamas son materiales seguros, y se relacionan en un porcentaje bajo y con una evidencia débil a efectos indeseables y enfermedades sistémicas.<sup>26</sup>

Por tanto la falta de datos objetivos y de argumentos científicamente probatorios no ha permitido establecer de forma conclusiva los riesgos neurológicos o renales, o eventual rol en el daño de la salud de niños o adultos, ni tampoco beneficios saludables por el retiro de amalgamas.

La OMS considera que todos los materiales actuales, incluida la amalgama, deberían estar disponibles para la población. Incluso advierte el probable riesgo de inequidad en salud por problemas de acceso a tratamientos eficaces y de bajo costo y por tanto establece que debería tomarse en cuenta esta valoración. No obstante ello, y en concordancia con la estrategia global de disminución de la utilización del mercurio (Convención de Minamata), la *Agence Nationale de Sécurité du Médicament et des Produits de Santé* (ANSM/ Francia) manifiesta la voluntad de disminuir los tratamientos dentarios con amalgama.<sup>25</sup>

Fuertes restricciones en el uso de amalgamas en algunos países (e incluso fundamento para prohibiciones) surgen a partir de la posibilidad de liberación de mercurio volatilizado por acciones de cremación de cuerpos con restauraciones dentales en amalgama. Ésta situación de importancia significativamente menor que la contaminación industrial, se puede superar eficazmente mediante captación y manejo controlado del mercurio en las técnicas de cremación.

## 5. LA AMALGAMA COMO MATERIAL DE RESTAURACIÓN

La amalgama posee una eficaz relación costo beneficio ampliamente probada por su fiabilidad y duración<sup>2</sup>, ya que sin precisar alta especialización para su instalación resulta manejada con éxito por generalistas, con resultados altamente predecibles (incluso iguales o superiores a algunas técnicas más modernas). Esto fundamenta lo señalado por distintos organismos internacionales (OMS, FDI, ADA), en donde la supresión para países subdesarrollados o poblaciones vulnerables instalaría problemas de salud pública al perderse estrategias con características adaptables al contexto.

Tanto por su menor necesidad de recambio y costo específico (humano y material), la amalgama puede ser de 1.5 a 3 veces más barata que las resinas o similares<sup>26</sup>. Por tanto los países que las sustituyan requerirán un gran esfuerzo económico adicional. Países ricos (Estados Unidos y Alemania) cuyos seguros valoraron la posibilidad de remover las amalgamas existentes para sustituirlas por materiales más modernos, han vuelto atrás en sus aspiraciones dado los altísimos derivados y entendiendo que los beneficios logrados no se compadecen con los enunciados. En efecto, además de que no se ha demostrado la condición deletérea del material la remoción supone volatilización de mercurio innecesaria y una nueva y masiva instancia de control de desechos.

*El consenso ampliamente aceptado es que, si no hay razones fundadas, se desaconsejan los programas masivos de remoción y sustitución de amalgamas, incorporando la idea de una sustitución gradual y un progresivo desuso (FDI, OMS).<sup>27</sup>*

## 6. CONTROL DEL MERCURIO EN EL CAMPO ODONTOLÓGICO

La manipulación de las amalgamas durante su instalación, remoción y gestión de desechos genera la necesidad de adecuados protocolos. Especialmente durante su instalación, el mercurio volatilizado puede ser absorbido por operadores y pacientes (aunque siempre en concentraciones mínimas). El personal dental (odontólogo, asistente, higienista) es el que ha presentado mayores rastros de contaminación en proporción comparada con la de pacientes asistidos.

La aparición de cápsulas predosificadoras, equipos de succión, trabajo con aislamiento de la pieza dentaria, control del aire ambiental, almacenamiento adecuado de los desechos, evitar el vertido cloacal y precauciones para paciente y operador son medidas que se encuentran descritas y acordadas por distintas organizaciones, las que debidamente puestas en práctica disminuyen sustancialmente los riesgos humanos y ambientales.<sup>28</sup>

## 7. CONVENIO DE MINAMATA

Uruguay suscribe a este convenio realizado en 2009 donde se establecen distintas metas y objetivos en el uso y control del mercurio industrial, de salud (vacunas, desinfectantes, amalgamas), agroquímicos y otros. Incluye también el concepto de abandono gradual del uso de la amalgama, promoviendo enfoques preventivos y uso de materiales alternativos.<sup>29</sup>

La FDI, la ADA y la OMS han descrito a las amalgamas como un material fiable, seguro y de difícil sustitución para países subdesarrollados. Sin embargo las mismas concuerdan primordialmente por el impacto ambiental que éstas generan (aunque sea mínima su contribución), ser sustituidas gradualmente para restringir nichos de mercurio por controlar.



## 8. ENFOQUE Y POSICIÓN DE LA FACULTAD DE ODONTOLOGÍA DE LA UNIVERSIDAD DE LA REPÚBLICA

Nuestra institución, desde los cambios de paradigma de sus planes de estudio (1993, 2001, 2011) hasta la postura de las áreas asistenciales de manejo (clínicas y preclínicas restauradoras) y enfoque de áreas específicas (Farmacología, Patología, Materiales Dentales), ha venido profundizando sobre la temática desde principios del año 2000.

En una primera etapa se incluyó la discusión y recomendaciones del uso y control del mercurio de las amalgamas (promoviendo el uso de cápsulas predosificadoras, recipientes de almacenamiento de desechos, divulgación de protocolos de manipulación e indicación) y valorando los conceptos de precaución en niños y embarazadas. Fue aprovechada la oferta de materiales alternativos de buenas características y probada eficacia ingresados en el mercado.

A partir de las jornadas institucionales de 2007 "Perspectivas futuras en el uso de la amalgama" se consolidan las líneas de trabajo por lo cual en una segunda etapa, 2008-2011, se incluyeron restricciones en la enseñanza práctica y teórica, así como en su aplicación clínica. Lo mismo también respondió a una verificable disminución de la demanda en pacientes, profesionales y docentes.

En una tercer etapa, de 2013 a la actualidad, se ha eliminado la enseñanza práctica, preclínica y clínica, manteniéndose su enseñanza teórica (para el conocimiento del material, indicaciones y riesgos del manejo mercurial y los protocolos existentes para reparaciones y remociones).

Se ha acordado una postura institucional de desestimulo en su uso y de la incorporación a pleno de materiales alternativos eficaces con cualidades no contenidas en la misma (estética, adhesión, menor desgaste de tejidos duros).

A esta postura se arriba luego de considerar los siguientes puntos:

- El contexto favorable del Uruguay por su población, geografía y relación profesional-número de pacientes, a la vez de una oferta adecuada de equipamiento y materiales para técnicas alternativas.
- El cambio de paradigma en la profesión: abordaje por enfoque de riesgo y tratamiento preventivo restaurador; promoción y fomento del estado de salud; prevención temprana contrapuesta al tradicional enfoque curativo restaurador. La aparición de materiales adhesivos estéticos que suponen alternativas eficaces (especialmente los de última generación) y la incorporación del concepto de Odontología Mínimamente Invasiva (ahorrando tejidos duros).
- La disminución en la demanda por parte de la población de restauraciones de amalgamas por razones estéticas o temor al mercurio.
- El menor uso y demanda de los profesionales que encaran soluciones alternativas.
- El acompañar criterios de distintos organismos (OMS, ADA FDI, DINAMA) que, en distintos congresos, jornadas, declaraciones y acuerdos, en particular el de Minamata, promueven conductas tendientes al control del mercurio, entre las cuales se incorpora el concepto de sustitución gradual de la amalgama como material restaurador.

En suma:

A pesar de que no se han demostrado fehacientemente daños significativos a la salud o al ecosistema, la Facultad de Odontología en base a las razones anteriormente enumeradas está promoviendo acciones concretas sobre el uso de amalgamas y del mercurio involucrado en su uso, en línea coherente con el Acuerdo de Minamata.

Se ha eliminado su enseñanza práctica del currículo divulgándose los protocolos de conocimiento y control mercurial, alentando su sustitución por materiales alternativos y no promoviendo o indicando su uso.

También se deja claro que hasta el momento no hay criterios científicos que avalen la remoción indiscriminada de las amalgamas como medida profiláctica y que de existir causa fundada (caries, estética, alergia localizada) la remoción de la misma se hará en base a protocolos establecidos de actuación clínica y control de sus desechos.

La utilización o no de la goma dique en el momento de remoción de una obturación de amalgama tiene un efecto irrelevante desde el punto de vista toxicológico, si bien en ese momento se produce un aumento en la absorción de Hg, ese aumento es transitorio y de baja intensidad, ya que las cifras de mercurio en orina y en sangre descienden por debajo de los niveles del momento de la remoción a los 100 días.<sup>15</sup> EL uso de la misma puede ser favorable para el profesional en la manipulación de los restos de manera práctica.

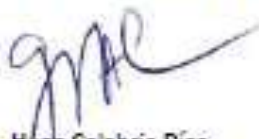
La implementación de la Ecofarmacovigilancia en la Facultad de Odontología tiene un enfoque ambiental y de salud pública.<sup>39</sup>

Al igual que otros elementos traza potencialmente tóxicos como el aluminio, el cadmio o el plomo, el mercurio utilizado en terapéutica contamina el medioambiente.<sup>9</sup>

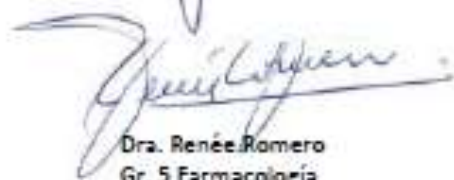
La Facultad de Odontología está comprometida en concientizar a la comunidad Universitaria en el correcto procedimiento de eliminación de los productos farmacéuticos, medicamentos y materiales dentales buscando aportar al concepto de creación y mantenimiento de ciudades sostenibles.

La Facultad de Odontología queda a disposición de las autoridades sanitarias para colaborar en la difusión, capacitación y puesta en práctica de estas líneas de trabajo en pos de compatibilizar la salud bucal y el control del mercurio en línea con los acuerdos internacionales.

Saludan con atenta consideración,



Dr. Hugo Calabria Díaz  
Decano



Dra. Renée Romero  
Gr. 5 Farmacología

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**VIETNAM CHEMICALS AGENCY**  
**MINISTRY OF INDUSTRY AND TRADE**  
The socialist republic of Vietnam

**THE NATIONAL FOCAL POINT TO  
THE MINAMATA CONVENTION**

*Hanoi, February 22<sup>nd</sup>, 2021*

To: Minamata Secretariat [mea-minamatasecretariat@un.org],  
Cc: Mr. Takafumi Anan [takafumi.anan@un.org]; Mr. Huy Nga [huynga2000@gmail.com]; Mrs. Lien To [tolien.hsph@gmail.com]; Mr. Charlie Brown [charlie@mercury-free.org]

Re: Provide information on phasing down the dental amalgam use in Vietnam under the Minamata Convention on Mercury

The Vietnam National Focal Point to the Minamata Convention on Mercury (Vietnam Chemicals Agency, Ministry of Industry and Trade) is pleased to inform the Minamata Secretariat of actions that Vietnam has been taking to phase down toward phase out the use of dental amalgam, as below:

1) On March 25, 2019, Health Services Administration Department - Ministry of Health issued an Official Letter no. 261/KCB-QLCT&CDT to all 63 provincial Departments of Health, central-level hospitals and health facilities of other Ministries to request: (1) Do not use dental amalgam for children under 15, pregnant and breastfeeding women from April 01, 2019; and (2) Develop the roadmap to phase out dental amalgam from January 01, 2021. This Department also request all dental clinics and chambers to use new materials with outstanding, safe for health and accessible features to replace dental amalgam (1).

2) Vietnam Odonto-Stomatology Association (VOSA), the national dental society, and an environmental and health NGO, Center for Community Health and Injury Prevention (CCHIP), have been working together on voluntary initiatives to stop dental amalgam use. On July 16, 2018 VOSA issued its Official Recommendation on phasing out dental amalgam for children under 15, pregnant and breastfeeding women by August 1st, 2018 and phase out for all by 2020 (2).

3) On June 25, 2020, VOSA and CCHIP sent an official joint letter to the Secretariat of the Minamata Convention affirming the availability of dental amalgam alternatives in Vietnam and confidence in successful transformation to a mercury-free dentistry (3).

References:

- (1) Official Letter no. 261 Vietnam MOH  
Translation: Official letter No.261 Vietnam MOH Translation
- (2) Recommendation of national dental society (VOSA)  
Translation: VOSA Recommendation translation
- (3) Joint letter VOSA and CCHIP to Minamata Secretariat

Yours sincerely, *HS*  
  
\_\_\_\_\_

Luu Hoang Ngoc  
Vice Director of Vietnam Chemicals Agency  
Vietnam National Focal Point to the Minamata Convention on Mercury

*(Translation)*

**MINISTRY OF HEALTH  
HEALTH SERVICES  
ADMINISTRATION DEPARTMENT**

**SOCIALIST REPUBLIC OF VIETNAM**  
**Independence – Freedom – Happiness**

Directive No: 261/KCB - QLCL&CDT  
On Dental Amalgam Phase-out

*Hanoi, Mar 25<sup>th</sup>, 2019*

To:

- Departments of Health of all provinces and cities of Vietnam,
- Central-level Hospitals, under the Ministry of Health,
- Health Facilities of Other Ministries.

In order to implement the Annex A-II of the Minamata Convention on Mercury, and the Official Recommendation of the Vietnamese Odonto-Stomatology Association (VOSA) on phasing down-to-out the Use of Dental Amalgam because it contains about 50% Mercury, which causes potential harmful effects on the environment and public health, especially children under 15 years old, pregnant and breastfeeding women,

Health Service Administration Department requests all odonto - stomatological examination and treatment facilities (dental clinics and chambers) nationwide to perform the following tasks:

1. Stop using dental Amalgam for children under 15, pregnant and breastfeeding women by April 1<sup>st</sup>, 2019;

2. Develop a roadmap to entirely stop using dental Amalgam in dentistry from January 1<sup>st</sup>, 2021.

Health Service Administration Department requests all health facilities to use new dental materials with outstanding, safe for health and accessible features to replace Amalgam./.

**Recipients:**

- As above;
- MOH Minister (for reporting purposes);
- MOH Deputy Minister, Nguyen Viet Tien (to report);
- Archive: Administrative files, Quality Control & Training dept.

**DIRECTOR GENERAL**

(signed and stamped)

**Prof. PhD. Dr. Luong Ngoc Khue**



**BỘ Y TẾ  
CỤC QUẢN LÝ  
KHÁM, CHỮA BỆNH**

**CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM  
Độc lập-Tự do - Hạnh phúc**

**Số 24/KCB - QLCL&CBT**

*Hà Nội, ngày 25 tháng 3 năm 2019*

V/v: khuyến cáo không sử dụng hỗn  
hợp nha khoa Amalgam

Kính gửi:

- Sở Y tế các tỉnh, thành phố trực thuộc Trung ương,
- Các Bệnh viện trực thuộc Bộ Y tế,
- Y tế các Bộ/ Ngành.

Thực thi Phụ lục A-II của Công ước Minamata và khuyến cáo của Hội Răng Hàm Mặt Việt Nam về hạn chế sử dụng Amalgam trong Nha khoa vì Amalgam là vật liệu hàn răng có chứa thủy ngân (khoảng 50%), có thể gây ảnh hưởng nguy hại tới môi trường và sức khỏe cộng đồng, đặc biệt là ảnh hưởng tới trẻ em dưới 15 tuổi, phụ nữ mang thai và cho con bú.

Cục Quản lý Khám, chữa bệnh đề nghị các cơ sở khám bệnh, chữa bệnh Răng Hàm Mặt trên toàn quốc thực hiện một số việc sau đây :

1. Không sử dụng Amalgam cho trẻ em dưới 15 tuổi, phụ nữ mang thai và cho con bú từ ngày 01/04/2019.
2. Xây dựng lộ trình ngừng sử dụng Amalgam trong Nha khoa từ ngày 01/01/2021.

Cục Quản lý Khám, chữa bệnh đề nghị các cơ sở khám bệnh, chữa bệnh Răng Hàm Mặt sử dụng các vật liệu nha khoa mới có tính năng vượt trội, an toàn với sức khỏe và dễ tiếp cận để thay thế Amalgam./.

*Nơi nhận:*

- Như trên;
- Bộ trưởng (để b/c);
- Thứ trưởng thường trực Nguyễn Việt Tiến (để b/c);
- Lưu: VT, QLCL&CBT.

**CỤC TRƯỞNG**



**Lương Ngọc Khuê**

*(Translation)*

**VIETNAM ODONTO-STOMATOLOGY  
ASSOCIATION (VOSA)**

No:124/HRHM

**SOCIALIST REPUBLIC OF VIETNAM  
Independence – Freedom – Happiness**

Hanoi, July 16th, 2018

To: Members of Vietnam Odonto-Stomatology Association

Since 2017, Center for Community Health and Injury Prevention (CCHIP), and World Alliance for Mercury-Free Dentistry have worked and discussed with Vietnam Odonto-Stomatology Association (VOSA) on a recommendation on dental amalgam phase-out.

According to requests of the aforementioned partners, Vietnam Odonto-Stomatology Association and its partners organized many scientific meetings and discussed related aspects of this issue.

On the occasion of the 6<sup>th</sup> Dental Scientific & Continuing Education Conference in Vinh city, Nghe An province (April 24-26, 2018), the VOSA's Executive Committee, odonto-stomatology scientists, dentists and dental practitioners, and the conference participants had a scientific forum on this issue, and entirely agreed to adopt a recommendation to limit the use of amalgam in dentistry.

Vietnam Odonto-Stomatology Association is pleased to send all members and dental colleagues this recommendation (attached).

Sincerely yours,

*Recipients:*

- As above;  
- CCHIP;  
- Archive

**VOSA'S PRESIDENT**

(signed and stamped)

**Prof. Trinh Dinh Hai**



## VIETNAM ODONTO-STOMATOLOGY ASSOCIATION

(Attached with VOSA's Official letter No. 124/HRHMTVN, dated July 16<sup>th</sup>, 2018)

### RECOMMENDATION

#### Phase-Down to Out the Use of Dental Amalgam

Dental Amalgam is recommended to not be used for children under 15, pregnant women and breastfeeding mothers by August 1<sup>st</sup>, 2018, and for all people by 2020. Because of the following reasons:

1. Dental Amalgam contains ~ 50% Mercury, which has possible harmful effects on the environmental & human health, especially children under 15 & pregnant/ breastfeeding women.
2. Dental Amalgam is a major source of mercury exposure for dentists and dental practitioners while WHO reported that exposure to mercury at any dose can affect human health, especially in the fetus and young children.
3. Currently, various alternative materials are safer, more available and affordable.
4. Numerous dental associations and organizations worldwide recommended "Dental Amalgam phase-down" due to harmful effects on the environment & human health.

HỘI RĂNG HÀM MẶT VN

Số: 124 /HRHM

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM  
Độc lập – Tự do – Hạnh phúc

Hà Nội, ngày 16 tháng 7 năm 2018

Kính gửi: Hội viên Hội RHM VN

Từ năm 2017, Trung Tâm Nghiên Cứu Sức Khỏe Cộng Đồng và Phòng Chống Chấn Thương ( CCHIP ) – Bộ Y tế, và Liên Minh Thế Giới về Nha Khoa Không Thủy ngân đã nhiều lần đề nghị và thảo luận với hội RHMVN về khuyến cáo không sử dụng Amalgam trong Nha khoa.

Theo đề nghị tâm huyết của các đối tác nói trên, Hội RHMVN và đối tác đã tổ chức nhiều buổi sinh hoạt khoa học và thảo luận các khía cạnh liên quan.

Nhân Hội nghị Khoa Học và Đào Tạo Liên Tục RHM lần thứ 6 tại thành phố Vinh, Nghệ An ( 24 -26/4/2018 ), Ban Chấp Hành Hội RHMVN, các nhà khoa học, các bác sỹ RHM, và các đại biểu tham dự đã có Diễn Đàn Khoa Học về các vấn đề liên quan, và đã thống nhất thông qua khuyến cáo hạn chế sử dụng Amalgam trong Nha khoa.

Hội RHMVN trân trọng chuyển tới các quý ủy viên BCH và quý hội viên Hội RHMVN bản khuyến cáo ( kèm theo ).

Trân trọng cảm ơn!

Nơi nhận:

- Như trên,
- CCHIP
- Lưu.





## HỘI RĂNG HÀM MẶT VIỆT NAM

VIỆT NAM ODONTO-STOMATOLOGY ASSOCIATION

(Kèm theo công văn số 124 /HRHMTVN ngày 16/7/2018 )

### KHUYẾN CÁO

#### Hạn chế sử dụng Amalgam trong nha khoa

Không nên sử dụng Amalgam cho trẻ em dưới 15 tuổi, phụ nữ mang thai, phụ nữ cho con bú từ ngày 1/8/2018 và nên ngừng sử dụng Amalgam từ năm 2020. Lý do:

1. Amalgam là vật liệu hàn/trám có chứa thủy ngân ( khoảng 50% ), có thể gây ảnh hưởng nguy hại tới môi trường, tới sức khỏe cộng đồng, đặc biệt là ảnh hưởng tới trẻ em dưới 15 tuổi, phụ nữ mang thai và phụ nữ cho con bú.
2. Amalgam còn là nguồn phơi nhiễm thủy ngân lớn đối với các y bác sỹ. Tổ chức Y tế ( WHO ) đã có thông báo là tình trạng phơi nhiễm với thủy ngân ở bất kỳ liều lượng nào cũng có thể ảnh hưởng tới sức khỏe của cộng đồng, đặc biệt là đối với thai nhi và trẻ nhỏ.
3. Hiện nay, đã có nhiều vật liệu nha khoa với tính năng vượt trội, an toàn mà dễ dàng tiếp cận để thay thế Amalgam.
4. Nhiều Hội nha khoa các nước và các tổ chức thế giới đã có khuyến cáo và đề cập ngừng sử dụng Amalgam do có các tác dụng bất lợi tới môi trường và sức khỏe.





Hanoi, June 25<sup>th</sup>, 2020

To: Secretariat of the Minamata Convention on Mercury  
11-13, Chemin des Anémones - 1219 Châtelaine, Switzerland

**RE: *We are ready for Mercury-Free Dentistry***

Dear Minamata Secretariat,

Vietnam Odonto-Stomatology Association (VOSA), the national dental association with its local chapters in the provinces, and Center for Community Health and Injury Prevention (CCHIP), a Hanoi-based environmental and health NGO intensely involved in implementing the Minamata Convention on Mercury, jointly submit this letter to the Secretariat of the Minamata Convention on Mercury.

We have worked together with our government to accelerate the transition to mercury-free dentistry. In Vietnam, the alternatives are technically and economically feasible. We are pleased to assist the Secretariat of the Minamata Convention on Mercury to provide information on the availability, the technical and economic feasibility, and the environmental and health of the non-mercury alternatives to dental amalgam.

Here is the experience of Vietnam.

In Vietnam, non-mercury alternatives to amalgam are available in both urban and rural areas. Because they are available, the Vietnam Ministry of Health's Health Service Administration Department advised its provinces and its dental offices to stop using amalgam for children under 15, pregnant women, and lactating women by April 01<sup>st</sup>, 2019. It further called for a roadmap to stop using amalgam in dentistry.<sup>[1]</sup> The goal is to end amalgam use in Vietnam in 2021.

Non-mercury alternatives benefit our environment by preventing dental mercury pollution. Approximately 52 tonnes of mercury is consumed for use in dental amalgam in East and Southeast Asia each year.<sup>[2]</sup> This mercury can eventually reach the environment and pollute the air via cremation, dental clinic emissions, municipal waste incineration, and sewage sludge incineration; the water via dental clinic releases not caught by separators and human waste; and the land via landfills, burials, and sewage sludge used as fertilizer.

Non-mercury alternatives benefit our health by reducing human mercury exposure and preserving tooth structure. Amalgam's elemental mercury can convert to methylmercury, and contaminate the fish that are important to many people's diets in Vietnam, so using non-mercury alternatives will not only reduce direct exposure to amalgam filling in the



mouth, but will also reduce this mercury exposure thorough fish too. Modern dentistry recognizes that amalgam placement requires the removal of more tooth structure than non-mercury alternatives, and emphasizes the importance of preserving tooth structure as an important health and cost advantage of non-mercury fillings.

Vietnam's health system is now quite modern. Although we are one of the 20 most populous countries in the world, with almost 100 million people, we survived the COVID-19 pandemic without a single death! Having ended amalgam already for the most vulnerable, we believe our health care system is capable of completing the transition to mercury-free dentistry on a rapid timetable.

Thank you for considering these experiences from Vietnam.

Sincerely,

**Prof. Dr. Trinh Dinh Hai**  
President, VOSA  
Hanoi, Vietnam

**Assoc. Prof. Nguyen Thi Thu**  
Director, CCHIP  
Hanoi, Vietnam

<sup>15</sup> Ministry of Health's Health Service Administration Department, Directive No: 251/KCB - QLCLSCBT (25 March 2019). <https://mercuryfreedentistry.files.wordpress.com/2020/03/vietnam-ministry-of-health-re-children-etc.png> (unofficial translation available at <https://mercuryfreedentistry.net/directive-no-251-of-moh-on-dental-amalgam-mar-25/>)

<sup>16</sup> UNEP/AMAP, Technical Background Report to the Global Mercury Assessment (2018). [https://wedocs.unep.org/bitstream/handle/20.500.11822/29631/igms\\_tbrn.pdf?sequence=1&isAllowed=y](https://wedocs.unep.org/bitstream/handle/20.500.11822/29631/igms_tbrn.pdf?sequence=1&isAllowed=y), p.3-39 (B1)



## Annex II

### Information on non-mercury alternatives to dental amalgam – submissions from Governments

Submissions from governments (African Region, Argentina, Brazil, Canada, EU, Japan, Jordan, Kenya, Moldova, Norway)

<b>1. Mercury-added product</b>	<i>Dental amalgam</i>
<b>2. Further description of the product</b>	<p>Dental amalgam has been used as a restorative material for centuries, in order to fill cavities caused by tooth decay and to repair tooth surfaces. It is an alloy of mercury and other metals (e.g. silver, tin, copper).</p> <p>Amalgam fillings are also known as “silver fillings” because of their silver-like appearance. Approximately 50 percent of dental amalgam is elemental mercury by weight. Mercury’s unique properties (it is the only metal that is a liquid at room temperature and that bonds well with powdered metal alloys) have made it an important component of dental amalgam that contributes to its longevity.</p>
<b>3. Information on the use of the product</b>	<p>Jordan</p> <p>In Jordan, the use and disposal of dental amalgam fillings (1,356 kg) is the main source of Mercury released to water (2,520 kg) and one of the main sources (246 kg) of mercury released to land (430 kg)<sup>1</sup>.</p> <p>EU</p> <p>Dental amalgam is the largest remaining use of mercury in the EU. The estimated annual demand for dental amalgam (EU28) amounted to 27-58 t of mercury in 2018. This represents a significant decrease, by approximately 43%, compared to the previous estimate 55-95 t of mercury a year in 2010<sup>1</sup>. It is estimated that in 2018, approximately 372 million dental restorations were carried out in EU28. Of these, only between 10% and 19% would have used dental amalgam. This share, however, varies significantly among Member States.</p> <p>Moldova</p> <p>The dentistry in Republic of Moldova, having been part of the Soviet Union, which rarely used any amalgam at all, has been very close to be mercury-free since the proclamation of independence in 1991. Due to complicated technology and harmful action on workers’ health care, amalgams were not used broadly in dentistry<sup>1</sup>. In addition, the dental amalgam raised aesthetic concerns and was applied only to molar teeth positioned distally in the oral cavity. In 2019, the country proudly stepped up and made the decision to end all amalgam use, by making a relevant prohibition in the Chemicals Law no. 277/2018<sup>2</sup>. It should be noted that even though other European countries ended amalgam with exceptions, the Republic of Moldova went further, ending all amalgam use as of this year, 2020.</p>

	<p>Argentina</p> <p>In Argentina, the Ministry of Health seeks to establish a plan to minimize the use of mercury in dentistry, setting goals with terms and reduction percentages, aimed at eliminating the use of dental amalgam by 2025.</p> <p>Japan</p> <p>In Japan, dental treatment with dental amalgam has no longer been covered by health insurance since the revision of the medical payment system in April 2016. Mercury-free alternatives for dental restoration have been listed as those covered by health insurance.</p> <p>Norway</p> <p>In Norway, dental amalgam has been used as a restorative material in dentistry for more than a century (Norwegian Board of Health, 1999). Most Norwegians today aged 50 years and older have many and extensive amalgam fillings in their teeth. The estimated use of mercury in new tooth fillings has been considerably reduced over the years (from 2 000 kg in 1985 to 840 kg in 1995, and close to zero in 2008, when the general use was banned) (Klif 2010a, 2010c). The quantity of amalgam in the population represents approximately 10 tons of mercury in Norway today, and it is expected that mercury release from existing fillings will continue for up to at least 30 years. (Skjelvik, 2012)</p>
<p><b>4. Information on the availability of mercury-free (or less-mercury) alternatives</b></p>	<p>EU</p> <p>The progressive substitution of dental amalgam with mercury-free materials (such as e.g. <i>composite resins, ceramics, and glass ionomer cements</i>) is already taking place. The overwhelming majority of EU manufacturers (95%) produce mercury-free materials, which represent a major share of the market.</p> <p>Moldova</p> <p>The materials used for dental restorations are mostly polymers, represented mostly by composite resin fillings and glass ionomer fillings. Today compomers, giomers, and dental porcelain inlays, gold inlays and full crowns are also used as alternatives to dental amalgam.</p> <p>Canada</p> <p>Non-mercury alternatives to dental amalgam, most commonly composite resins, are widely used in Canadian dental practices. Today, it is estimated that over 90% of sales of filling material in Canada are composite resin and less than 10% are dental amalgam.<sup>1</sup> The increase in frequency of use of non-mercury restoration</p>

	<p>materials is also reflected by imports of dental amalgam which have declined drastically over the last 12 years.<sup>2</sup> Nonetheless, there are still situations where composite resins, glass ionomers and other non-mercury alternatives to dental amalgam are not suitable or available for use due to technical, economic, and/or health reasons.</p> <p>Japan</p> <ul style="list-style-type: none"> <li>• Materials, primarily composed of resin, inorganic filler or resin and composite filler, polymerized chemically by mixing or by external energy, are used for filling of a tooth cavity or repair of artificial crowns.</li> <li>• Dental filling glass polyalkenoate cement, a type of cement that cures by a reaction between aluminosilicate glass powder and alkenoic acid aqueous solution or between a mixture of aluminosilicate glass-polyacid powder and water or organic acid aqueous solution, is used for tooth filling and restoration.</li> <li>• A dental filling material composed of a resin component and glass polyalkenoate cement for dental filling material may be used in the repair of artificial crowns.</li> <li>• A material made primarily of acrylic ester monomer and polymer, polymerized chemically by mixing or by external energy, is mainly used for filling of a tooth cavity or repair of artificial crowns.</li> </ul> <p>Brazil</p> <ul style="list-style-type: none"> <li>• The main approach of the Federal Government is to decrease the demand and need for dental filling of the population, encouraging and fostering oral health promotion and prevention. Additionally, it is important to mention that the composite resin and glass ionomer are the main mercury-free restoring materials used to treat dental caries.</li> <li>• The Atraumatic Restorative Treatment (ART), recommended by the Ministry of Health (BRAZIL, 2007; 2018) uses only hand instruments and does not require electrical dental equipment and piped water. Among other advantages, it is possible to perform the ART fillings outside the healthcare facilities and in specific populations, such as those geographically isolated. Nevertheless, it is important to emphasize that the restoring material used in this technique (glass ionomer) does not have the same physical and chemical properties and clinical performance as the dental amalgam, and its lifespan is shorter than the amalgam's. It is worth mentioning that, despite the technological evolution of glass ionomer cements, they show more wear and less resistance to fracture than resin and amalgam, which restricts their indication.</li> </ul>
<b>5.(i) Information on the technical feasibility of alternatives</b>	<p>EU</p> <ul style="list-style-type: none"> <li>• Given the high use of mercury-free materials across the EU, it can be assumed that the vast majority of dental facilities in the EU already have the equipment required for mercury-free</li> </ul>

	<p>restorations and that most, if not all, dentists master the necessary techniques.</p> <ul style="list-style-type: none"> <li>• Evidence has shown that mercury-free materials exhibit satisfactory mechanical properties, with a lower cavity preparation requirement for composites<sup>2</sup> as well as better aesthetics<sup>3</sup>. Four main factors influence the longevity of a filling: the material, the method of restoration, the dentist's skills, and the patient's dental hygiene. Mercury free materials are nowadays of good quality, effective restoration methods are widely available and dental schools are increasingly teaching the necessary skills. Dental hygiene should continue improving, thanks to public health communication. Hence, the longevity of restorations should further improve.</li> </ul> <p>Norway</p> <ul style="list-style-type: none"> <li>• Composite resin fillings are made of a type of plastic (an acrylic resin) reinforced with powdered glass. The color (shade) of composite resins can be customized to closely match surrounding teeth. They easily blend in with surrounding teeth and require minimal removal of healthy tooth structure for placement compared with dental amalgam. Composites require a bonding system for micromechanical adhesion to the tooth structure. But they may be less durable than dental amalgam and may need to be replaced more frequently.</li> <li>• Glass ionomer cement fillings are based on the reaction of silicate glass powder and polyalkenoic acid. These tooth-coloured materials were introduced in 1972 for use as restorative materials for small cavities. Glass ionomer cements have the ability to bond chemically to dental hard tissues and to release fluoride for a relatively long period. Their chief disadvantage is that they are limited to use in small restorations due to low resistance to fracture.</li> <li>• Resin-modified glass ionomers combine the traditional glass ionomer with a resin material. Such materials undergo both an acid-base ionomer reaction supplemented by a second resin polymerization initiated (usually) by a light-curing process. These materials are more fracture resistant than glass ionomers and combined with the ability of chemical bond to tooth substance, they are used for small restorations, especially in pediatric dentistry, in addition to the same indications as glass ionomers.</li> </ul> <p>African region</p> <ul style="list-style-type: none"> <li>• Mercury-free alternatives provide superior dentistry to rural Africa. Mercury-free alternatives like glass ionomer can be less expensive and more accessible than amalgam. Atraumatic restorative treatment (ART) was developed in eighties in East Africa to address this weakness of amalgam, because (i) ART does not need electricity or expensive equipment; (ii) ART can address most cavities in children; and (iii) its clinics can be portable, reaching into remote villages. The World Health Organization's Collaborating Centre for Oral Health Services</li> </ul>
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	<p>Research praises ART in its training manual, which explains, “ART offers an opportunity for preventive and restorative dental treatment under field conditions where there is lack of electricity and modern dental facilities.”<sup>1</sup> As African countries are now moving to the paradigm of prevention and no more through cure response in dental caries treatment, it is high time to spread prevention techniques using mercury-free alternatives. ART is one of the suitable methods to achieve this goal.</p> <ul style="list-style-type: none"> <li>• For African dentists and African dental schools, mercury-free alternatives mean superior dentistry, 21st century dentistry, for this region. The governments work closely with, and consult with, dentists and dental schools. African dentists know how to use the alternatives, and in general prefer them; many of them have stopped using amalgam for a decade already.</li> </ul> <p>Canada</p> <p>Non-mercury alternatives to dental amalgam have been shown to have higher rates of failure and secondary caries and so must be replaced more frequently than amalgam restorations.<sup>3</sup> It is for this reason that non-mercury alternatives to dental amalgam may not be suitable for certain individuals or populations; particularly for those with a high frequency of caries and poor oral hygiene or for those for whom regular dental visits are unavailable.<sup>4, 5</sup> Financial and physical access to dental care remains a barrier for vulnerable groups including: remote communities, Indigenous peoples, refugees and immigrants, people with disabilities, elderly people, and low-income Canadians.<sup>6</sup></p> <p>Argentina</p> <p>In Argentina, dental professionals continue to show some reluctance to replace dental amalgam, since in terms of occlusion of dental cavities it continues to be the material that shows the best performance.</p> <p>Brazil</p> <ul style="list-style-type: none"> <li>• In remote regions of difficult access, where there is no timely dental assistance and reduced availability of dental equipment, as well as for persons in vulnerable situations, the dental amalgam may be the material of choice of oral health professionals, as it is more suitable for those situations. It is known that the use of dental amalgam requires low technological capacity, while composite resin requires a dental curing light in good conditions of use to provide a good polymerization of the material (process of converting the resin into the plastic/solid state by light). Additionally, an adhesive system with good properties is necessary, allowing the resin to adhere to the dental substrate.</li> </ul>
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	<ul style="list-style-type: none"> <li>The Indigenous Health Care Subsystem Report identified that, despite the increase in the total number of fillings carried out between 2015 (n=150,440) and 2018 (n=270,946), factor that may be associated with the increased access to dental services, that, in addition to developing assistance activities, also perform actions directed to prevention of dental caries and other oral health problems. Despite the fact that the total number of fillings increased, the report identified that there was a decrease in the proportion of amalgam fillings in comparison with other materials. Amalgam fillings represented 10.3% (n=15,565) of the fillings performed in 2015, and this percentage dropped to 9.2% (n=25,008) in 2018. These numbers reflect a reduction trend in the use of the amalgam and an increase in the use of amalgam substitutes over time, with significant regional differences.</li> </ul>
<b>5.(ii) Information on the economic feasibility of alternatives</b>	<p>EU</p> <p>The difference between the prices of dental restorations per type of material is relatively small due to improvements in mercury-free restoration techniques. Furthermore, the price difference between dental amalgam and mercury-free materials has decreased.</p> <p>Moldova</p> <p>Moldova is a small country and at an income level below other countries in Europe. Yet, this country could be an example to the world that the transition to mercury-free dentistry is economically feasible.</p> <p>African region</p> <ul style="list-style-type: none"> <li>The cost of keeping amalgam is much greater than the transitional cost to mercury-free dentistry. To have amalgam-based dentistry will be very expensive: (1) continuing amalgam means buying separators for every dentist, at 1000 to 2000 US dollars, and servicing them for hundreds of dollars per year; (2) building multi-million dollar mercury-waste facilities; (3) building a transportation infrastructure to get the mercury waste from dental clinics and hospitals to the waste facilities. It is important to note that these infrastructure costs will only catch the mercury waste from dental clinics; the mercury coming from human bodies during their lives and after burial or cremation will not be caught and will go into the environment. By contrast, the cost to shift to alternatives – some of which cost more, some of which do not – is a far less costly approach for Africa, and much of it (adjusting dental schools and clinics) is a one-time expense.</li> <li>Because of the environmental damage from amalgam's mercury, mercury-free alternatives cost much less. Amalgam's price is lower than composite only because the polluter does not pay – so we governments must pay for amalgam's environmental damage. Counting environmental damages, amalgam is much more expensive than composite.<sup>2</sup></li> </ul>

## Canada

- Restorations performed with non-mercury materials are generally more expensive than dental amalgam in Canada (about \$171 for amalgam compared to \$219 for composite) and do not last as long (11.5 year lifespan for amalgam compared to 8 year lifespan for composite).<sup>7</sup> The higher costs of placement as well as the need to replace composite fillings more frequently is an important consideration for the discussion on the availability and economic feasibility of non-mercury alternatives to dental amalgam. About 94% of dental care in Canada is provided by the private sector, but 32% of Canadians do not have dental insurance and pay the total cost of dental visits out-of-pocket.<sup>8,9</sup> Even with dental insurance, there are typically costs associated with visits as insurers only cover a portion of dental fees.<sup>10</sup> The use of dental care services in Canada is largely influenced by insurance coverage and the ability to pay out-of-pocket for the expenses. Over six million Canadians (or about one in five) avoid dental visits each year because of the cost.<sup>11, 12</sup>
- In addition to the concerns about the affordability of dental care for individuals, the cost differential between composite fillings and amalgam fillings can have real financial implications on the sustainability and effectiveness of publicly funded oral health programs which have the goal of providing low cost or no cost dental care to vulnerable populations. Increased operational costs to these programs mean that fewer patients can be treated. Poor oral health can lead to impaired physical health, low self-esteem, increased absences and poor performance at school or work.<sup>13</sup> The health risks from untreated caries are much higher than the risks from dental restorations, regardless of their material.
- In discussing the economic feasibility of non-mercury alternatives to dental amalgam, it is important to consider the cost implications of using more expensive non-mercury restoration materials in the broader context of overall health and accessibility of dental care, for both publicly funded programs as well as individuals. In Canada, access to dental care can also be limited by physical distance. For example, the Inuit Oral Health Survey conducted in 2008-2009 found that fewer than half of the study participants received dental care in the past year, even though few reported that costs were a factor in their decision.<sup>14</sup> For Inuit and other First Nations groups, the federal government provides some health and dental insurance. However, many Inuit and remote communities do not have a resident dentist and rely on irregular visits from fly-in dentists who reside in southern Canada. Often only the most serious cases can be seen due to time limitations, otherwise people must be flown in and out of the community for treatment and dental emergencies.<sup>15</sup> The issues of access to care shown in this example applies to other remote and Indigenous communities in Canada who do not have resident dentists.

<p><b>6. Information on environmental and health risks and benefits of alternatives</b></p>	<p>EU</p> <ul style="list-style-type: none"> <li>• Dentist representative organisations have expressed concerns regarding a lack of available information on mercury-free materials, as well as the safety profile and biocompatibility of certain materials, some of which contain Bisphenol A (BPA) and nano-sized particles (particles with a size from 1 to 100 nm). Due to a lack of comprehensive scientific evidence, the potential direct and indirect impacts of mercury-free materials remain uncertain. Available scientific reviews concluded that release of BPA from certain dental materials was associated with only negligible health risks<sup>4</sup> and exposure to BPA is within the Tolerable Daily Intake<sup>5</sup>. However, the 2015 BPA risk assessment by the European Food Safety Authority, which reduced the Tolerable Daily Intake for BPA from 50 to 4 µg/kg bw/day, is currently under review.</li> <li>• Dental amalgam, on the other hand, causes significant emissions of mercury to air, water, and soil. Emissions to air were estimated<sup>6</sup> to be 19 t over the dental amalgam life cycle (2012, EU27<sup>7</sup>). Emissions to water<sup>8</sup> by dental clinics were estimated to be 3 t (2010, EU27), which will reduce as the Regulation mandates dental practices to be equipped with high level retention dental amalgam separators.</li> <li>• The presence of mercury in wastewaters is problematic for the residues (sludge) from urban wastewater treatment plants. Depending on the type of wastewater treatment, mercury may end up in sludge from wastewater plants. Mercury emissions from dental amalgam to soil, estimated at 8 t (2010, EU27), are primarily due to the spreading on land of such sludge.</li> </ul> <p>Canada</p> <ul style="list-style-type: none"> <li>• In terms of the health risks of non-mercury alternatives to dental amalgam, concerns have been raised about the safety of composite resins as restoration materials because many composite resin materials contain BPA derivatives, most commonly bisphenol A glycidyl methacrylate (Bis - GMA; CAS no. 1565 - 94 - 2), bisphenol A ethoxylate dimethacrylate (Bis - EMA, CAS no. 41637 - 38 - 1), and bisphenol A dimethacrylate (Bis - DMA; CAS no. 3253 - 39 - 2).<sup>16,17</sup> A number of studies have shown that several substances, including BPA, can leak from some composite filling materials.<sup>18, 19</sup> However, in 2010 the World Health Organization concluded that dental materials were unlikely to be an important source of BPA exposure to humans and likened the exposure risks from composite resins to food packaging and drink containers.<sup>20</sup> A subsequent assessment conducted by the European Food Safety Authority agreed with this conclusion.<sup>21</sup></li> <li>• The environmental risks of non-mercury alternatives to dental amalgam have not been well studied. Part of the difficulty in quantifying the risk to the environment is that there are many formulations of composite material and their chemical compositions are often proprietary.<sup>23</sup> This poses a challenge to</li> </ul>
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	<p>assess the environmental risks of the substances used both individually and as mixtures. For example, BPA is used as a raw material to synthesize resin monomers that are used in composite fillings; however, there is limited information about how much BPA enters the environment as a result of the manufacture, use, and disposal of composite fillings.<sup>24</sup> The lack of information on non-mercury alternatives does not allow for a robust environmental risk assessment to be performed.<sup>25,26,27</sup></p> <ul style="list-style-type: none"> <li>• Unlike dental amalgam, there are no separators, chairside traps or special disposal protocols for waste consisting of composite materials, meaning the majority of composite waste material is ultimately deposited in municipal wastewater systems or landfills.<sup>28</sup> The creation of microparticulates (including microplastics) and nanoparticles during the filing and shaping, CAD/CAM milling, and removal of composite fillings are an additional consideration in discussing the environmental risks of non-mercury filling materials. The contributions of dental materials to BPA and micro/nanoparticulate concentrations in landfills and wastewater are unknown and may warrant further investigation.<sup>29</sup></li> </ul> <p>African region</p> <p>Mercury-free alternatives means Africa will not be the dumping ground for mercury amalgam, nor the “charity” center for other regions wanting to offload amalgam, nor a source for illegal gold mining.</p>
<p><b>7. Other relevant information pursuant to Decision MC-3/2</b></p>	<p>African region</p> <p>As proof of the feasibility of mercury-free alternatives, across the continent the transition to mercury-free dentistry has begun in Africa. Mercury-free alternatives work in Africa. Many years ago, Zambia (2016) and Mauritius (2013) ended amalgam use for children. Going farther, the Tanzania Guidelines (2020) end amalgam for all children and for all women of childbearing age in 2023. Dental schools, such as the Université de Félix Houphouët-Boigny in Abidjan and all Federal universities of Nigeria, are shifting their curriculum to mercury-free dentistry. Entire hospital systems, such as the Cameroun Baptist Convention, and public dental clinics of Madagascar, have ended amalgam use entirely. Military hospitals in Abidjan, Antananarivo (Madagascar), Cotonou (Benin) have definitively abandoned amalgam use for several years. In the region famous for leapfrogging technologies, mercury-free alternatives are a prime example of skipping an unneeded step.</p> <p>Norway</p> <ul style="list-style-type: none"> <li>• Norway has phased out the use of dental amalgam. New filling materials were introduced in Norway in the 1970s and were gradually preferred for aesthetic reasons. Focus on dental amalgam as an environmental problem emerged during the 1980s as part of a broader policy to limit emissions of mercury.</li> </ul>

	<ul style="list-style-type: none"> <li>• In 1991 the health authorities issued guidelines recommending dentists to reduce the use of dental amalgam, and new guidelines from 2003 required that other materials than dental amalgam should be considered as the first choice in tooth fillings. Preventive use of fluoride has also contributed to improved dental health and reduced use of dental amalgam.</li> <li>• A requirement to have an approved dental amalgam separator installed in all dental clinics was introduced in 1994. Requirements to control the mercury air emissions from crematoria with more than 200 cremations per year were implemented in 2007.</li> <li>• Norway introduced a general ban on the use of mercury in products from 2008. Limited exemptions for dental amalgam use were applied until the end of 2010.</li> </ul>
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## Annex III

### Information on non-mercury alternatives to dental amalgam – submissions from non-party and other organizations

#### Submissions from non-party and other organizations

<i>Submitter</i>	<i>Non-mercury alternatives referred in the submission</i>	<i>Technical and Economic Feasibility</i>	<i>Environmental and Health Risks and Benefits</i>	<i>Other information</i>
AGENDA, Tanzania	<ul style="list-style-type: none"> <li>• Composite resin</li> <li>• Glass ionomer</li> </ul>	Mercury-free dental fillings are available and in use in Tanzania.		
American Dental Association (ADA) and International Association for Dental Research (IADR)	<ul style="list-style-type: none"> <li>• Composite resin</li> </ul>	<ul style="list-style-type: none"> <li>• Amalgam fillings have a higher survivability rate and longevity.</li> <li>• Amalgam fillings have advantage in cost and ease of placement.</li> <li>• Composite resin fillings are deemed more attractive.</li> <li>• Expenditures toward prevention are cost saving.</li> </ul>	Although amalgam remains a safe, effective, and inexpensive restorative option, there are general environmental concerns relating to mercury.	
Asian Center for Environmental Health	<ul style="list-style-type: none"> <li>• Composite resin</li> <li>• Glass ionomer</li> <li>• Compomer</li> </ul>	The complete phase out of mercury amalgam is feasible to implement.		
Ban Toxics				The Department of Health, the Philippines, issued Administrative Order (AO20), adopting a three-year national phase-out of dental amalgam.
Center for Public Health and Environmental Development		Most reliable and safer non-mercury alternatives are increasingly available		MOHP, Nepal, took a decision on banning uses of Mercury Dental Amalgam in Nepal



<b>Submitter</b>	<b>Non-mercury alternatives referred in the submission</b>	<b>Technical and Economic Feasibility</b>	<b>Environmental and Health Risks and Benefits</b>	<b>Other information</b>
(CEPHED), Nepal		in Nepal at competitive prices.		from August 21, 2019.  <ul style="list-style-type: none"> <li>For pregnant and breast-feeding women and children below 15 years: complete ban</li> <li>For other age groups: ban within 5 years upon the availability of alternatives.</li> </ul>
Chicago Declaration for Ending Mercury Use in the Dental Industry (North American Dental Professionals)		Non-mercury alternatives are available, and technically and economically feasible.	Non-mercury filling materials prevent mercury exposure to our patients and dental personnel and allow for less tooth destruction than amalgam.	Approximately half of American dentists never use dental amalgam.
Children's Environmental Health Foundation (CEHF), Zambia	<ul style="list-style-type: none"> <li>Glass ionomer cement (GIC)</li> <li>Composites</li> <li>Cention N</li> </ul>	<ul style="list-style-type: none"> <li>GICs are readily available, technically feasible, and cost (15-17 USD per item).</li> <li>Composites are readily and locally available, technically feasible, esthetically good, and cost (40-60 USD).</li> <li>Cention N is capable of releasing acid—neutralizing ions, and costs (24.50 USD)</li> </ul>	<ul style="list-style-type: none"> <li>Alternatives are environmentally friendly.</li> <li>GIC releases fluoride, thus promotes tooth strength.</li> <li>For GIC and composites, there is no need to cut healthy tooth structure.</li> <li>Cention N involves strong material for posterior load-bearing restoration, high flexural strength.</li> </ul>	Zambian dentists ended amalgam for children 20 years ago.

<b>Submitter</b>	<b>Non-mercury alternatives referred in the submission</b>	<b>Technical and Economic Feasibility</b>	<b>Environmental and Health Risks and Benefits</b>	<b>Other information</b>
Consumers for Dental Choice, US			<ul style="list-style-type: none"> <li>• Dental amalgam's elemental mercury can convert to methylmercury in the human body.</li> <li>• Dental Amalgam poses a risk to vulnerable populations.</li> <li>• Dental amalgam's mercury pollutes water via dental clinic releases and human waste.</li> <li>• Dental amalgam's mercury pollutes air via cremation, dental clinic emissions, and sludge incineration.</li> </ul>	
Centre de Recherche et d'Education pour le Development (CREPD)	<ul style="list-style-type: none"> <li>• Glass ionomers</li> <li>• Composites</li> </ul>	<ul style="list-style-type: none"> <li>• The ART technique does not require dental drill, plumbed water, or electricity.</li> <li>• The treatment process needs no anaesthetic because pain and discomfort are rare.</li> <li>• This approach is entirely consistent with modern concepts of preventive and</li> </ul>	<ul style="list-style-type: none"> <li>• Mercury from dental amalgam can harm the human health and the environment.</li> <li>• Dental amalgam waste management in Cameroon was not the best.</li> </ul>	

<i>Submitter</i>	<i>Non-mercury alternatives referred in the submission</i>	<i>Technical and Economic Feasibility</i>	<i>Environmental and Health Risks and Benefits</i>	<i>Other information</i>
		<p>restorative oral care.</p> <ul style="list-style-type: none"> <li>• The installation and running cost of a separator (for dental amalgam) is very high and few dentists can afford that.</li> <li>• There is a lack of dexterity and/or instrumentation of individual dentists to appropriately place mercury-free alternatives on the patient teeth.</li> <li>• If externalities are excluded in the cost calculation, the cost of dental amalgam is lower.</li> </ul>		
DCMFA	<ul style="list-style-type: none"> <li>• Glass ionomer</li> <li>• Dental nanocomposites</li> <li>• Gioners</li> </ul>	<ul style="list-style-type: none"> <li>• High viscosity glass ionomer restoratives are now widely available and affordable in developing economies.</li> <li>• Glass ionomer restoratives are biocompatible restoratives that bind chemically to tooth tissues.</li> <li>• Glass ionomers have hydrophilic properties, they can be placed in the wet oral environment.</li> </ul>	<ul style="list-style-type: none"> <li>• There is unnecessary removal of healthy tooth tissue to enhance the retention of dental amalgam.</li> <li>• Amalgam is an environmental and clinic pollutant because it is 41%-50% mercury.</li> <li>• There is a lack of systems and technologies for sorting, collection,</li> </ul>	A 'leapfrogging' phase down strategy with direct transition to mercury free dentistry will safeguard human health and the environment.

<i>Submitter</i>	<i>Non-mercury alternatives referred in the submission</i>	<i>Technical and Economic Feasibility</i>	<i>Environmental and Health Risks and Benefits</i>	<i>Other information</i>
		<ul style="list-style-type: none"> <li>The restoration matures with time (increasing hardness).</li> <li>It is capable of ionic exchange with demineralized dentine and enamel.</li> </ul>	<p>transport and treatment of mercury wastes generated from dental clinics in developing countries.</p> <ul style="list-style-type: none"> <li>Mercury-free dentistry (minimum intervention dentistry) enhances infection control.</li> </ul>	
Environment and Social Development Organization (ESDO), Bangladesh	<ul style="list-style-type: none"> <li>Composite</li> <li>GIC</li> </ul>	<ul style="list-style-type: none"> <li>More than 75% of dentists in Bangladesh use composites.</li> <li>In Bangladesh, non-mercury alternatives are available in both urban and rural regions.</li> </ul>		<ul style="list-style-type: none"> <li>Bangladesh Dental Society (BDS) stopped using amalgam for children under 15, pregnant women, and lactating women from 30.06.2018.</li> <li>Bangladesh Army, NAVY and Air force have combinedly phased out dental amalgam in their treatments in 2018.</li> </ul>
European Center for Environmental Medicine	<ul style="list-style-type: none"> <li>Composites</li> <li>Glass ionomers</li> <li>Compomers</li> </ul>	<ul style="list-style-type: none"> <li>Non-mercury alternatives to amalgam are available and feasible.</li> <li>Most dentists in Europe practice mercury-free dentistry, and all</li> </ul>	<ul style="list-style-type: none"> <li>Amalgam damages healthy tooth matter, weakens tooth structure, and fractures teeth.</li> <li>Mercury-free materials offer</li> </ul>	<ul style="list-style-type: none"> <li>Sweden and Norway have phased out amalgam use.</li> <li>Finland, the Netherlands, and Denmark use amalgam</li> </ul>

<i>Submitter</i>	<i>Non-mercury alternatives referred in the submission</i>	<i>Technical and Economic Feasibility</i>	<i>Environmental and Health Risks and Benefits</i>	<i>Other information</i>
		<p>dentists (certainly all under age 70) know how to use mercury-free fillings.</p> <ul style="list-style-type: none"> <li>The annual failure rate of composite fillings in the posterior region (2.2%) is statistically not different from that of amalgam fillings (3.0%).</li> </ul>	<p>benefits of preserving tooth structure and strengthening teeth.</p> <ul style="list-style-type: none"> <li>Many studies have warned against the use of amalgam in people with kidney impairments.</li> <li>Amalgam's known risks keep increasing while no harm from mercury-free fillings has been found in half a century.</li> </ul>	<p>for only 1% of all fillings.</p> <ul style="list-style-type: none"> <li>70% of the EU Member States have less than 10% amalgam use or have filed phase-out plans.</li> </ul>
FDI World Dental Federation		<ul style="list-style-type: none"> <li>Alternative restorative materials are still not "technically and economically feasible" for many resource-limited settings</li> <li>Dental amalgam is the most affordable treatment option in many cases both in terms of cost of placement and how long it lasts.</li> </ul>	Increased research and development of quality mercury-free materials for dental restorations, including their potential environmental impact is needed.	
Action Group for Promotino and Protection to Flora and Fauna (GAPROFFA), Benin	<ul style="list-style-type: none"> <li>Composite</li> <li>Glass Ionomer Cement (GIC)</li> </ul>	<ul style="list-style-type: none"> <li>Accessibility to alternatives in Benin is limited by patients' lack of information and sometimes on "supposed" financial means.</li> </ul>	Non-mercury alternatives are good for health and the environment.	Generally, it is patients with a fairly high education and with very rigorous oral hygiene who are requesting for composites (used in about 90% of



<b>Submitter</b>	<b>Non-mercury alternatives referred in the submission</b>	<b>Technical and Economic Feasibility</b>	<b>Environmental and Health Risks and Benefits</b>	<b>Other information</b>
		<ul style="list-style-type: none"> <li>Alternatives to amalgams are available in Benin even if few dentists have strong knowledge and practice on how to fill patients' cavities.</li> <li>The price of composite varies between 50-120 USD, which is relatively expensive for a common citizen.</li> </ul>		dental clinics in Cotonou-Benin).
International Academy of Oral Medicine and Toxicology (IAOMT)	<ul style="list-style-type: none"> <li>Composite</li> <li>Gold alloys</li> <li>Ceramics</li> </ul>	<ul style="list-style-type: none"> <li>Composite fillings perform as well as amalgam when comparing failure rates and replacement filling rates.</li> <li>The real cost of using amalgam far outweighs the cost of using mercury-free composite.</li> </ul>	<ul style="list-style-type: none"> <li>Scientific literature shows the health hazards of using dental mercury amalgam.</li> <li>Composite resins present a lower risk for chemical exposures.</li> </ul>	The Precautionary Principle is essential to consider when evaluating environmental and health risks and benefits.
Kisiwani Conservation Network, Kenya	<ul style="list-style-type: none"> <li>Composites</li> <li>GIC</li> <li>Artificial dental crowns</li> <li>Porcelain</li> <li>Gold</li> </ul>	<ul style="list-style-type: none"> <li>Alternatives exist, are in active use and affordable in both public and private clinics in Mombasa, Kenya.</li> <li>Practitioners are well-trained and possess requisite infrastructure.</li> <li>Composites and some crowns are cheaper than amalgam.</li> </ul>	<ul style="list-style-type: none"> <li>Mercury from dental amalgam gets to the environment, due to poor waste collection, weak compliance and also through cremation.</li> </ul>	

<b>Submitter</b>	<b>Non-mercury alternatives referred in the submission</b>	<b>Technical and Economic Feasibility</b>	<b>Environmental and Health Risks and Benefits</b>	<b>Other information</b>
		<ul style="list-style-type: none"> <li>County Department of Health offered fair fiscal investments for alternatives.</li> </ul>		
Latin American Centre for Environmental Health (LACEH)	<ul style="list-style-type: none"> <li>Glass ionomer (ART technique)</li> </ul>	<ul style="list-style-type: none"> <li>ART uses only hand instruments to place the filling.</li> <li>ART can be done in villages without electricity and outside of dental clinic setting.</li> <li>Amalgam can be costly and is not always widely available, especially for disadvantaged populations.</li> <li>ART costs only half as much as amalgam.</li> <li>Glass ionomers, whether via ART or otherwise, have a preventive component.</li> </ul>		<ul style="list-style-type: none"> <li>Uruguay uses a small percentage of dental amalgam and is moving quickly towards eliminating it.</li> <li>In Chile, very little percentage of dental amalgam is used, nearly none.</li> <li>Bolivia has already got a regulation to end dental amalgam in children and pregnant women.</li> </ul>
SRADev Nigeria		<ul style="list-style-type: none"> <li>89% of the dental clinics in Enugu State of Nigeria now use non-mercury alternatives, which are available.</li> <li>UBTH, one of the largest public hospital in Edo State of Nigeria, has phased out amalgam use for</li> </ul>		

<i>Submitter</i>	<i>Non-mercury alternatives referred in the submission</i>	<i>Technical and Economic Feasibility</i>	<i>Environmental and Health Risks and Benefits</i>	<i>Other information</i>
		children since 2018.		
Timis County College of Dentists (TCCB), Romania		Despite environmental concerns, for some patients in specific groups, the use of dental amalgam may be the only feasible treatment option that can best meet all clinical circumstances and patient needs.	<ul style="list-style-type: none"> <li>• There is no evidence that dental amalgam presents a direct health risk to people who have amalgam restorations.</li> <li>• However, through contamination of the environment, dental amalgam may contribute indirectly to the risk to human health due to mercury.</li> </ul>	The use of dental amalgam is no longer allowed in Romania for the treatment of children under 15, pregnant or breastfeeding women or temporary teeth, unless the dentist considers it strictly necessary.
Vietnam Odonto-Stomatology Association (VOSA) and Center for Community Health and Injury Prevention (CCHIP), Viet Nam		In Vietnam, non-mercury alternatives are available in both urban and rural areas and technically and economically feasible.	<ul style="list-style-type: none"> <li>• Mercury from dental amalgam can eventually reach the environment and pollute the air via cremation, dental clinic emissions, municipal waste incineration, and sewage sludge incineration; the water via dental clinic releases not caught by separators and human waste; and the land via landfills, burials, and sewage sludge used as fertilizer.</li> </ul>	Vietnam MoH advised its provinces and its dental offices to stop using amalgam for children under 15, pregnant women, and lactating women by 1 April 2019.

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			<ul style="list-style-type: none"> <li>Amalgam's elemental mercury can convert to methylmercury and contaminate the fish that are important to many people's diet in Vietnam.</li> <li>Amalgam placement requires the removal of more tooth structure than non-mercury alternatives.</li> </ul>	
World Alliance for Mercury Free Dentistry (WAMFD): Arab States	<ul style="list-style-type: none"> <li>Composites</li> <li>Glass ionomers</li> <li>Copolymers (modified composites)</li> </ul>	<ul style="list-style-type: none"> <li>Alternatives are readily available and widely used in Arab countries.</li> <li>Alternatives help to preserve natural tooth structure.</li> </ul>	<ul style="list-style-type: none"> <li>A study on air of dental clinics in Lebanon and Morocco finds that the use of mercury containing amalgam in the dentistry sector leads to high concentrations of mercury inside the closed spaces of dental care clinics.</li> </ul>	
Dentist's Committee for a Mercury Free Africa (DCMFA)	<ul style="list-style-type: none"> <li>Glass ionomer</li> <li>Dental nanocomposites</li> <li>Giomers</li> </ul>	<ul style="list-style-type: none"> <li>High viscosity glass ionomer restoratives are now widely available and affordable in developing economies.</li> <li>Glass ionomer restoratives are biocompatible restoratives that</li> </ul>	<ul style="list-style-type: none"> <li>There is unnecessary removal of healthy tooth tissue to enhance the retention of dental amalgam.</li> <li>Amalgam is an environmental and clinic pollutant</li> </ul>	A 'leapfrogging' phase down strategy with direct transition to mercury free dentistry will safeguard human health and the environment.

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		<p>bind chemically to tooth tissues.</p> <ul style="list-style-type: none"> <li>• Glass ionomers have hydrophilic properties, they can be placed in the wet oral environment.</li> <li>• The restoration matures with time (increasing hardness).</li> <li>• It is capable of ionic exchange with demineralized dentine and enamel.</li> </ul>	<p>because it is 41%-50% mercury.</p> <ul style="list-style-type: none"> <li>• There is a lack of systems and technologies for sorting, collection, transport and treatment of mercury wastes generated from dental clinics in developing countries.</li> <li>• Mercury-free dentistry (minimum intervention dentistry) enhances infection control.</li> </ul>	
WAMFD: SIDS-CSOs		The danger of dental mercury in limited-space societies of island states makes the transition to mercury-free dentistry essential.	The mercury from dental amalgam going into fish is called a “secondary poisoning” by SCHER, the European Union Committee of Scientists, who studied amalgam’s harms.	<ul style="list-style-type: none"> <li>• By order of its president, the self-governing territory of New Caledonia stopped all amalgam use in September 2019.</li> <li>• Via voluntary agreement of its dentists and the government, St. Kitts and Nevis Islands ended all amalgam use.</li> <li>• In 2014, the Mauritius Ministry of Health and Quality of Life ended the use</li> </ul>



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				<p>of amalgam for children under age 10 and for pregnant women.</p> <ul style="list-style-type: none"> <li>• Madagascar ended amalgam use in public programs and in military hospitals.</li> </ul>
WAMFD	<ul style="list-style-type: none"> <li>• Composite (mostly used)</li> <li>• Glass ionomer materials (mostly for children)</li> <li>• Compomers</li> </ul>	<ul style="list-style-type: none"> <li>• The Swedish Chemical Agency stated at INC1 in 2010 that the alternatives to dental amalgam are “Available, Affordable and Effective”.</li> <li>• Increasingly available in both developed and developing nations.</li> <li>• Alternatives are now available as a liquid/powder to be mixed together by hand prior to use.</li> <li>• The materials are also available in a light hardening form and premixed in tubes or capsules.</li> <li>• Alternatives, e.g. through ART, can serve population lacking traditional dental care.</li> <li>• Like amalgam, the use of the</li> </ul>	<ul style="list-style-type: none"> <li>• The mercury from dental amalgam can pollute the environment, and high levels of mercury vapour exposure may cause potential toxic effects endangering patients and dental professionals.</li> <li>• Mercury can be both toxic and allergenic at the same time.</li> <li>• Low-dose chronic mercury exposure from dental amalgam can be associated with a number of neurological and developmental conditions.</li> <li>• There have been no reports of any damage to the environment from the use of composite,</li> </ul>	<ul style="list-style-type: none"> <li>• The “Precautionary Principle” must apply to all dental materials especially as dental amalgam is the source of the greatest body burden of mercury in humans.</li> </ul>

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		<p>light hardening materials, however, does require an equipped dental clinic and access to electricity.</p> <ul style="list-style-type: none"> <li>• A variety of shades are available when aesthetics is a consideration.</li> <li>• Composites and dental amalgam can be considered equal when considering the cost of a filling, but today's composite fillings have been shown to last longer than dental amalgam.</li> <li>• Bulk-fill composites can be placed into a cavity slightly quicker than amalgam.</li> <li>• Non-mercury alternatives to dental amalgam require less healthy tooth tissue removal than dental amalgam and in the case of composite produce a stronger filled tooth.</li> <li>• The real cost of dental amalgam is not borne by</li> </ul>	<p>compomer or glass ionomers.</p> <ul style="list-style-type: none"> <li>• Alternative materials present no risk to human health.</li> </ul>	

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		the user or recipient but by society as a whole and is and will be substantial.		
WAMFD: Scientific literature review		<ul style="list-style-type: none"> <li>• Mercury-free dental fillings are available in both developed and developing nations.</li> <li>• Many countries have phased-out amalgam, while many others are ending amalgam in programs.</li> <li>• Mercury-free fillings are long lasting, user-friendly and facilitate future repairs.</li> <li>• The technical superiority of mercury-free alternatives eliminates cost differences.</li> <li>• Mercury-free filling techniques (e.g. ART) can be less expensive and more accessible.</li> <li>• Mercury-free fillings eliminate the high environmental costs of dental mercury that governments must bear.</li> </ul>	<ul style="list-style-type: none"> <li>• Mercury-free fillings preserve tooth structure.</li> <li>• Mercury-free fillings can help prevent future caries.</li> <li>• Mercury-free fillings are safe for health and the environment.</li> </ul>	